Supreme Court, U.S.
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B4

No. _____

In the

Supreme Court of the United States

VALER V. SECAREA, JR.,
Plaintiff, Appellant and Petitioner

v.

REGENTS OF THE UNIVERSITY
OF CALIFORNIA,
KALYANAM SHIVKUMAR, M.D.,
DAVID CESARIO, M.D.,
CHARLES SWERDLOW, M.D.,
Defendants and Respondents

PETITION FOR WRIT OF CERTIORARI AND APPENDIX A, VOLUME 1 OF 2

After a Decision by the California Court of Appeal,
Fourth Appellate District, Division Three

Valer V. Secarea, Jr.
12 Amberwicke
Dove Canyon, CA 92679
949-589-3843
In Propria Persona

QUESTIONS PRESENTED

Question One:

Nadine Secarea was killed when a medical device experiment to which she was surreptitiously subjected at the University of California, failed to perform as envisioned. [It should be noted that the University of California is a branch of California Government: California Constitution, art. IX, § 9(a)].

Is California's policy (and that of other states) of treating surreptitious medical and human subject experimentation as a species of medical practice/malpractice a deprivation of both substantive and procedural due process protections under the Fourteenth Amendment to the U.S. Constitution?

Question Two:

Nadine named the physicians who would perform her surgery. She stipulated that no students be involved in her care beyond "observation." But, instead of the surgeons she chose, a student-fellow performed the surgery as part of his training. Moreover, the California Court Of Appeal ruled that the student's qualifications were "good enough" for Nadine.

Is government conscription of patients under false pretenses for use as objects of medical training inherently a violation of Constitutional protections

guaranteed by the Fourteenth Amendment's Due Process Clause; and/or personal privacy said to be protected by the Bill of Rights or its penumbras or among those rights reserved to the people by the Ninth Amendment as well as the protections afforded under the First and Fifth Amendment?

Question Three:

Valer's counsel was forbidden from speaking to any evidentiary issue at the hearing on the summary judgment which is at issue in this case, even though California makes provision to be so heard.

Is the right to due process and equal protection denied when a court arbitrarily refuses to allow a party to be heard on the issues upon which a judgment depends?

Question Four:

The government actors in this case claimed and were granted government immunity pursuant to their surreptitious conduct of the human subject experimentation.

Can the state of California grant government employees immunity from liability for acts of surreptitious human subject experimentation on unknowing and unsuspecting patients where Congress, through such agencies as the FDA, has made these requirements specifically applicable to the states?

PARTIES TO PROCEEDING

The parties to the proceedings are set forth in the case caption.

Respondents Regents of the University of California, Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow, M.D., are defendants and respondents below.

Irvine Regional Hospital and Medical Center, a separate party to the appeal in the court below, is not a party to the issues this petition raises and has no interest in the outcome.

CORPORATE DISCLOSURE STATEMENT

Petitioner, Valer V. Secarea, Jr., husband of Nadine F. Secarea, the decedent in this case, is an individual. See Rule 29.6.

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PETITION FOR WRIT OF CERTIORARI IN A NUTSHELL: MEDICAL RESEARCH OR MEDICAL PRACTICE?

In United States, et. al. v. Stanley, 483 U.S. 669, 107 S. Ct. 3054, 97 L. Ed. 2d 550, 55 U.S.L.W. 5101, Justice O'Connor, concurring in part and dissenting in part, at page 710, commented:

> [...] the United States military played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, ante, at 687, and the standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the "voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts." United States v. Brandt (The Medical Case), 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, p. 181 (1949). If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much.

This Petition[1] calls upon this Court to make that guarantee of due process about which Justice O'Connor spoke, not the view of one or two justices, but a holding of the Court, at least under the facts of this case.

It is in this context that Petitioner-Appellant-Plaintiff Valer V. Secarea, Jr.[2] respectfully petitions for

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[1] In the text to follow, page references preceded by no letter identify pages in the petition. Pages preceded by the letter "A" refer to Appendix A, this volume (Petition Volume-I). Likewise, all page numbers preceded by the letter "B" refer to Appendix B, which is entirely contained in Petition Volume II. The section symbol, "§" refers to paragraphs of the Second Amended Complaint, while "¶" refers to paragraphs of declarations.

Where matters in the record, not included in the appendices are referred to, "RT" refers to the Reporter's Transcript. "CT" refers to Clerk's Transcript, preceded by the volume number. "SAC" followed by a paragraph reference refers to the indicated paragraph in the Second Amended Complaint. AOB is the Appellant's (this Petitioner's) Opening Brief in the Court of Appeals, ARB, Appellant's Reply Brief, APFR the Appellant's Petition for Rehearing in the California Court of Appeals and SPFR the Petition for Review to the California Supreme Court.

[2] As in previous briefs, parties are identified:ppellant-plaintiff-Petitioner, Valer V. Secarea, Jr., ("Valer" or "Secarea") on behalf of himself and decedent wife, Nadine Francia Secarea ("Nadine"), defendants and respondents, Irvine Regional Hospital and Medical Center ("Irvine Regional"), Regents of the University of California ("Regents"); Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow., M.D., (Corresponding to the Court of Appeals opinion, Regents and Drs. Shivkumar, Swerdlow and Cesario are sometimes "UCLA Defendants.") And, as carried over from previous briefs, and the experimentation that spawned this case, Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow., M.D.,

a writ of certiorari to review the summary judgment determination of the California Court of Appeals for the Fourth District, Division 3 in the above-entitled matter involving surreptitious human subject medical research[3] and student-doctor training at the University of California at Los Angeles (UCLA), which, along with the inattentiveness of emergency room personnel,[4] ultimately resulted in the demise of Petitioner's wife, decedent Nadine Francia Secarea.

The events which bring the case to this Court began when Nadine hired Drs. Charles Swerdlow and. Kalyanam Shivkumar to personally perform an elective cardiac catheter ablation procedure[5,6] at UCLA Medical Center in order to relieve the symptoms of her cardiac

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sometimes Respondent Researchers, given that it was their covert medical experimentation activities which are at the heart of this petition.

[3] "Medical experimentation" and "human subject experimentation" (or "HSE") are sometimes used interchangeably.

[4] The case against the operators of the emergency room (Irvine Regional) and its physicians is not implicated in this petition.

[5] Appendix B-189 (Declaration of defense expert, Andrea Natale, M.D., in support of Regents, et. al., Motion for Summary Judgment, ¶21).

[6] Appendix B-165: 18 September 2003 letter from Charles Swerdlow, M.D., to Michael Brodsky, M.D., ("Swerdlow Letter") describing the procedure agreed upon to treat Nadine. (Referred in the record of this case as Limited Empirical Pulmonary Vein Isolation Procedure or LEPVI).

arrhythmia.[7]

About three weeks post procedure Nadine experienced neurological symptoms. She telephoned Dr. Swerflow for guidance, but his only advice was to "wait and see." A short time later, Nadine lost consciousness and was rushed emergently to Irvine Regional Hospital and Medical Center, where she died several days later.[8]

The cause of death resulted from an atrio-esophageal fistula, essentially a hole, "burned" through Nadine's heart wall and into the esophagus – which allowed insufflation of air into her circulatory system, which in turn led to multiple air embolisms and their associated fatal consequences.[9, 10]

At about the time of Nadine's death and afterward, Drs. Swerdlow and Shivkumar explained to husband Valer how, during Nadine's surgery, they were conducting a study to evaluate the theoretical possibility of using an anesthesiologist's temperature probe to detect the conditions leading to the very complication

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[7] Appendix B-65 - B-? (SAC §§ 111-141: Nadine Selects Her Surgical Team); B-200 - B-203, (Declaration of Valer V. Secarea, Jr., ("Valer's Declaration") ¶¶109-141); B-219 - B-223 (18 September 2003 email between Dr. Swerdlow and Nadine discussing how Drs. Swerdlow and Shivkumar work as a team); B-225 - B-231 (1 December 2003 email between Dr. Swerdlow and Nadine re: choice of surgical team).

[8] Appendix B-76 - B-79 (SAC §§148-154); B-209 - B-213 (Valer's Declaration ¶¶38-51).

[9] Natale op. cit. Appendix B-190, ¶24.

[10] Appendix B-9 (SAC §15, footnote 2).

that killed Nadine.[11]

The "Respondent Researchers" later published and presented the results of this study at symposia.[12]

Drs. Swerdlow and Shivkumar also revealed that the surgery performed on Nadine had been largely done by a student, one Dr. David Cesario. When confronted with the broken promise that they would personally perform the procedure, Dr. Swerdlow's only reply was: "how do you think we train doctors?" [13]

After gathering facts which indicated that the medical device experiment to which Nadine had been covertly subjected was governed by FDA (U.S. Food and

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[11] Appendix B-79 - B-99 (SAC §§155-202: The Experimental Form of the Ablation Procedure Revealed); B-212 - B-217, (Valer's Declaration, ¶¶46-62); B-233 - B-241 (October 2004 email correspondence between Valer and Dr. Swerdlow ("Valer's Email") re: esophageal temperature sensing performed on Nadine. This is an email "thread," which must be read "bottom-up." The original communication begins at Appendix B-239 and the last communication of the transcribed thread begins at B-235).

[12] Appendix B-99 - B-102 (SAC §§203-211; Publication of "Less Than Entirely True" Research Results); Petition Appendix B-243 (Cesario D, Shivkumar K, Valderrabano M, Wiener I, Swerdlow C. Esophageal temperature monitoring during left atrial catheter ablation for atrial fibrillation. *J Am Coll Cardiol* 2005; 45 Suppl A:114A.) See also, Appendix B-247 (Conte J, ACC 2005 Annual Session Highlights, *J Am Coll of Cardiol* Vol. 45, No. 11, Suppl B, June 7, 2005:30B–2B)

[13] Appendix B-107 - B-108 (SAC §§219-221: Training Dr. Cesario at the Expense of Nadine's Life); Valer's Declaration, op. cit. Appendix B-212 - B-213, ¶¶46-62.

Drug Administration), regulations[14] husband Valer's counsel filed suit for damages in Nadine's death, premised on the theory that Nadine did not consent to the medical experimentation to which she was subjected and could not absent Respondent Researchers strict adherence to the federal requirements.[15]

But, even after the "Respondent Researchers" in this case explained their experimentation to Valer, provided him with test data gathered from Nadine's participation,[16] identified the test article,[17] published their results and *bragged about the study* [18] at symposia, the Courts considering this case ruled that no federal regulations are involved, no experiment took place, the Respondent Researchers are entitled to government immunity for the consequences of non disclosure of the

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[14] Appendix B-20 - B-64 (SAC at §§44-108: Protection of Human Subjects in Experimentation. Specifically, the clinical study at the core of this litigation purported to rely on an abrupt temperature rise to control the application of RF energy during the ablation (tissue burning) process, from an instrument that was neither designed or approved by the FDA for that purpose. Such a clinical investigation requires an IDE (Investigational Device Exemption) from the FDA: Appendix B-31 - B-38 (SAC §§69-85: FDA IDE Approval Required for Medical Device Research) as well as Nadine's informed consent: Appendix B-38 - B-40 (SAC §§85-88).

[15] Appendix B-10 (SAC §17); Appendix B-20 - B-64 (SAC §§44-108: Protection of Human Subjects in Experimentation)

[16] Appendix B89 - B-90, (SAC at §180).

[17] Appendix B-95 - B-96 (SAC §§193-194).

[18] Appendix B-99 - B-102, (SAC at §§203-211: Publication of "Less Than Entirely True"Research Results).

medical research, Nadine's choice of physician was legally irrelevant[19] and granted summary judgment.

The main contention in this cause is that human subject experimentation is not a practice of medicine and the FDA regulations governing medical device studies[20] cannot be ignored by California courts.[21] Lastly, the Constitution's guarantee of personal autonomy precludes governments' conscripting unsuspecting and objecting patients into serving as objects of training and experimentation.

OPINIONS BELOW

The rulings of Orange County California Superior Court, the trial court, on Respondent Researchers Demurrers to the Second Amended Complaint is reproduced in this volume at Appendix A-3 - A-14. The summary judgment ruling is at Appendix A-19 - A-27, the unpublished opinion of the California Court of Appeals ("Opinion") is at A-31 - A-62, while the modified Court of Appeals opinion ("M-Opinion") is at Appendix A- 65 - A-68.

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[19] The Opinion at p.4 (Appendix A-33) describing student "ghost surgeon" Dr. Cesario's "qualifications," and at p.21 (Appendix A-60), is all but saying that a student learning to do a procedure was "good enough" treatment for Nadine , so long as no harm could be shown. But, there was harm, Nadine was killed.

[20] Protection of Human Subjects in Experimentation, op cit.

[21] The Opinion at p.22 (Appendix A-60) indirectly refers to the descriptions in Appendix B-20 through B-64 as "unspecified statutes and regulations."

STATEMENT OF JURISDICTION

The California Court of Appeals rendered its judgment in this case on 20 November 2008. A timely petition for rehearing was denied on 22 December 2008, but resulted in a modification to the Court of Appeals opinion. A timely petition for discretionary review to the California Supreme Court was denied on 18 February 2009. (See Appendix A-69.)

The jurisdiction of this Court is now invoked under 28 U.S.C. § 1257 (a).

CONSTITUTIONAL & STATUTORY PROVISIONS

Constitutional and statutory provisions are as cited in the Table of Authorities. The full text of provisions most relevant to this Petition is found in Appendix A, and as annotated in the Second Amended Complaint starting at Appendix B-1 and the Motion and Request for Judicial Notice ("RFJN"), for the FDA's interpretation of its regulations, beginning at Appendix B-251.

STATEMENT OF THE CASE

A. This Case is About Surreptitious Medical Experimentation on Unsuspecting Patients Who are Used then Discarded

1. The focus of this litigation is the federal regulations which govern human subject medical device studies[22]

The gravamen of this case is found in the allegations of federally regulated medical experimentation of the complaint.[23] However, the trial court and Court of Appeal in this case denied the federal regulations were applicable,[24] or presented for

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[22] Appendix B-1 - B-156 (SAC).

[23] Appendix B-20 - B-40 (SAC §§44-84: describes protection of human subjects in medical device experimentation under the FDCA as applied to the facts alleged.)

[24] See the trial court's ruling on demurrers to the Second Amended Complaint. Even after this Petitioner's very detailed 38 page (of 92 pages) exposition of how Respondent Researchers own descriptions of the device experiment to which they subjected Nadine violated the various California and federal statutes and regulations, as well as the regulations of the University of California (Appendix-B-2 - B-65, B-78 - B-106), the trial court states without explanation:

> Plaintiff was given an opportunity to amend the complaint to state any statutory violations by the government defendants. Plaintiff continues to fail to plead the requisite statute necessary to maintain a cause of action. (Appendix A-12)

consideration[25] even though Petitioner-Appellant-Plaintiff's Opening Brief cast regulation as "standard of care." [26] Not only this, but the Regents, et. al. claimed government immunity, which the trial court granted,[27] and the Court of Appeal apparently affirmed.[28] Note that this action granted immunity from FDA device study informed consent requirements found in 21 CFR 50.[29]

In so doing, the California Courts raised a new set of constitutional issues regarding deprivation of this Petitioner's rights to due process and equal protection of the laws. Petitioner argues that the Supremacy Clause, the 5th and 14th Amendment to the U.S. Constitution preclude ignoring the regulations and likewise prelude the case from being decided exclusively in a common law medical malpractice framework. Each issue framing the questions in this Petition is discussed in relation to its occurrence in the courts below. (cf. *Chambers v. Mississippi*, 410 U.S. 284 (1973)). That is, the record as a whole, beginning with the SAC, shows

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[25] It bears repeating that the Court of Appeal in its opinion at p.22 (Appendix A-60) indirectly refers to the descriptions in Appendix B-20 through B-64 as "unspecified statutes and regulations."

[26] Appendix A-99 (AOB extract at pp. 33-35 "Regulations as a standard of care").

[27] Appendix A-10 ("Public employees are immune ..."); Appendix A-60 (sustaining demurrers).

[28] 1.CT.260-261; AOB 42..

[29] Appendix B-34,35 (SAC §78).

how the constitutional issues evolved (cf. *Webb v. Webb*, 451 U.S. 493, 496 [101 S. Ct. 1889, 68 L. Ed. 2d 392, 49 U.S.L.W. 4500] (1981)), even if they are not cited "book and verse." (cf. *Daugharty v. Gladden*, 257 F.2d 750, 758 (CA9 1958)). But ultimately, whether the claims made are based on a federal right is itself a federal question for this Court to decide. (*Angel v.Bullington*, 330 U.S. 183, 189 (1947)).

Lastly, if the issues in this petition of mixed California, federal and constitutional jurisprudence somehow lacks the appropriate "federal character," Petitioner asks the Court to consider plain error, in the interests of justice, as the basis for its review. See 28 U.S.C 2106 (authorizing this Court to "require such further proceedings to be had as may be just under the circumstances"); R. Stern & E. Gressman, *Supreme Court Practice* § 6.27, p. 460 (5th ed. 1978) See also *Vachon v. New Hampshire*,414 U.S. 478 (1974); *Wood v. Georgia*, 450 U.S. 261, 265, n. 5 (1981).

2. Dr. Cesario confirmed that Nadine was subjected to a medical device study, made an object of student training, then left to die

During the pendency of the appeal process, on or about 8 December 2006, attorneys for the Emergency Room physicians who are defendants in this case (but not involved in the appeal), took the deposition of defendant and respondent, "ghost surgeon" Dr. David Cesario. The annotated deposition excerpts[30] provide

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[30] Appendix B-355 - B-401.

some essential insights as to why this court should review this case.

In his deposition, Dr. Cesario described himself (at the time of Nadine's procedure) as a trainee: "... an apprentice in learning to do procedures..."[31] as the SAC alleges.[32,33]

Dr. Cesario somewhat hesitatingly acknowledged that Nadine had been subjected to a medical experiment,[34] and that Nadine's procedure was performed in reliance on the untested capabilities of the temperature probe at issue in this case.[35] He also intimated that the study had no scientific basis. Respondent Researchers only *hoped it would work*.[36]

Dr. Cesario also described the presentations and publication of this research.[37] His testimony corresponds nearly to the allegations of the SAC, except that the colloquium of which Dr, Cesario spoke was the American Heart Association, where Dr. Shivkumar was ostensibly the presenter rather than the 2005 ACC Scientific Session, where Dr. Swerdlow was presenter.[38]

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[31] Appendix B-357 - B-358.

[32] Appendix B-14 (SAC §30)

[33] Appendix B-107 - B-108 (SAC §§219-221).

[34] Appendix B-369, B-370.

[35] Appendix B-374 - B-375.

[36] Appendix B-360.

[37] Appendix B-370 - B-373.

[38] Appendix B-99 - B-102.

Lastly, Dr. Cesario revealed that Dr. Swerdlow refused to come to Nadine's aid when he learned she had been struck down by what Respondent Researches did to her. Thomas Rockett, Plaintiff-Petitioner's trial attorney, inquires:

> MR. ROCKETT: Do you know whether any doctor, including yourself, made any effort to see the patient at Irvine Medical?
>
> DR. CESARIO: I suggested to Dr. Swerdlow that we should drive down and go evaluate her, and he did not think we should.[39]

Note also that Dr. Cesario regarded Nadine's condition to be a surgical emergency.[40] If that was so, where, this Petitioner asks rhetorically, was the team of experts from UCLA to aid Nadine in her life and death struggle?

With these basic events in mind, the issues this Petitioner asks this court to consider are described.

WHY REVIEW SHOULD BE GRANTED

A. This Case Involves Nation-wide Matters of Life and Death

This case presents some of the most pressing matters of interest to all citizens of this country -- protecting innocent and unsuspecting patients from

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[39] Appendix B-394.

[40] Petition Appendix B-399 - B-400.

surreptitious human subject experimentation, in this case, by state government. These are nation-wide matters which implicate not only rules and regulations, but federal constitutional protections involving rights granted under the concept of personal liberty embodied in the Fourteenth Amendment's Due Process Clause; or in personal privacy said to be protected by the Bill of Rights or its penumbras or among those rights reserved to the people by the Ninth Amendment. (See generally, *Roe et al. v. Wade*, 93 S.Ct. 705 [410 U.S. 113] (1973))

1. General Counsel for the University of California revealed that laws prohibiting surreptitious medical experimentation on unsuspecting patients are not enforced

California Health & Safety Code § 24170, et. seq., (Protection of Human Subjects in Medical Experimentation Act or PHSMEA), provides for protection of subjects involved in clinical research including adherence to Part 46 of Title 45 of the Code of Federal Regulations in some circumstances not relevant to the present litigation.

But, in the 20 December 1996 letter, on page 2, University Counsel Joanna Beam states:

> The California Department of Health Services and the California Office of the Attorney General are charged with enforcement of the provisions of the Act. Rumors have circulated that these departments have not and do not

intend to enforce the provisions of the Act. [41]

As this Petition will show, it appears that Ms. Beam's statement has a palpable ring of truth to it: covert human subject experimentation in California is conducted, almost unhindered.

2. Human subject experimentation regulation is not effective

Human subject researchers in California appear to be accountable to no one for their injurious actions.[42] Petitioner discovered that five patients were killed in experimentation prior to Nadine's death, but could find no indication that either the California Attorney General or California Department of Health Services, or anyone else, took any action against the responsible parties.[43] This is a situation that pleads for constitutional review.

In *Moore v. Regents of University of California* (1990) 51 Cal.3d 120, 129 [271 Cal.Rptr. 146, 793 P.2d 479], the California Supreme Court held that:

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[41] Appendix B-157 - B-163, Joanna. Beam letter, attached to the SAC, as Exhibit-1 ("Exhibit A" in Appendix. B)

[42] After all, how is it that the Respondent Researchers in this case could be so open about their research, explaining it to Petitioner, publishing, giving presentations and yet, both the trial court and the Court of Appeal say no experimentation occurred?

[43] Petitioner recognizes that his "investigative efforts" may have fallen short, as well.

> (1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.

Petitioner's experience indicates that this edict is entirely inadequate from the regulatory perspective of this case. A few examples[44] taken from communications of the FDA (Food and drug Administration) and United States Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP) will help to show why.

a. University of California a culture of non-compliance with the law

In a 1994 report produced by the the United States Department of Health and Human Services, Office for Protection from Research Risks (OPRR), the

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[44] These examples and documents, as well as many others, were submitted to the Court of Appeal in a 78 page "Motion and Request for Judicial Notice," ("RFJN") which was denied. (See Opinion, page 22 (Appendix A-61)

The motion was in the form of a PDF document submitted both on paper and on CD. When the PDF version was opened, most documents as well as legal citation references were retrieved from the internet, thus providing "original documents" for review.

The motion is reproduced, at Appendix B-251 - B-342.

predecessor to the current Office for Human Research Protections (OHRP), human subject research at UCLA was characterized by one critic as a "culture of noncompliance with the law" The attached excerpt[45] from that report explains why, including experimentation without legally valid informed consent,[46] the very issue in this case, as well apparently falsifying records.[47]

It seems not much has changed at the University of California since the 1994 OPRR Report. Patients such as Nadine, continue to be subjected to surreptitious human subject experiments, and medical records are still being falsified, apparently with impunity.[48, 49]

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[45] Appendix B-343 - B-349: Office for Protection from Research Risks (OPRR). Evaluation of human subject protections in schizophrenia research conducted by the University of California, Los Angeles. Rockville, MD: Office for Protection from Research Risks; 1994, Attachment M. (Note that fully 25 of the 102 pages of this document, obtained by way of a FOIA request, were redacted, sometimes whole sections, such as "Attachment L." (B-349)

[46] Appendix B-345, item 1.

[47] Appendix B-347, item 12.

[48] Appendix B-353 ("Records Falsified," front page story, Orange County Register, 26 September 2008).

[49] With his MSJ, Dr. Swerdlow submitted two documents alleged to be e-mails, dated September 24, 2004, 12 days after Nadine's death, which purported to address scheduling Nadine's procedure. (3 CT 703, 699-701; AOB 11-12).

b. Three dead in 2004 UCSF covert device experimentation

An FDA warning letter [50] dated 25 March 2004, to the University of California at San Francisco, describes violations of federal regulations, including failure to adhere to the stated research protocol associated with the FDA-issued IDE (p. 2), failure to obtain informed consent (pp. 4-5) and attempts to conceal medical research under a guise of "emergency" and "compassionate" use (p. 6).

c. Two killed in 2003 UCSF covert experimentation

In a 13 January 2003 DHHS OHRP warning letter [51] to the University of California, San Francisco, it was revealed that two patients were killed in research that] was conducted without review or approval by the UCSF IRB, as required by DHHS regulations, and without obtaining the legally effective informed consent of the subjects.

d. UCSF 2003 research disguised as "standard of care"

In a 25 July 2003 DHHS OHRP letter to the

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[50] Appendix B-303;
http://www.fda.gov/foi/warning_letters/archive/g4595d.pdf

[51] Appendix B-305;
http://www.hhs.gov/ohrp/detrm_letrs/YR03/jan03b.pdf

University of California, San Francisco,[52] significant deviations from informed consent requirements were described, and, at page 9, there appears to be an admission that research was masquerading as "standard of care, to wit:"

> Regarding '*Both types of [fluid management] methods are considered standard of care*', we agree that this phrase is suboptimall. While the specific interventions in the management strategies are considered standard of care, the actual strategies themselves are experimental.

Petitioner asserts that this tactic is similar to how Nadine was conscripted into the experimentation conducted by Respondent Researchers: they masked their experimentation with the appearance of "treatment."

e. No consent from 89 subjects in 2002 UCSF research

An 8 February 2002 DHHS OHRP letter to the University of California, San Francisco (p. 2), revealed that in one study, 36 of 43 subjects were unable to provide legally effective informed consent and in

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[52] Appendix B-305;
http://www.hhs.gov/ohrp/detrm_letrs/YR03/jan03b.pdf

another, 53 of 62 could not give consent.[53]

f. UCLA warned about informed consent in 2001

A 24 October 2001 DHHS OHRP letter[54] to the University of California at Los Angeles, DHHS OHRP, describes, at page 2, a memorandum regarding human subject experimentation at UCLA, to wit:

> In June 2000, you distributed a memorandum to all UCLA faculty, students, and staff stating that "no UCLA faculty, staff, or students may conduct human subject research without obtaining prospective IRB approval or a certified Claim of Exemption from IRB review.

But, Respondent Regents have not lived up to this policy because Nadine and other patients have been subjected to surreptitious human subject experimentation since that time.

g. UCLA warned about research safety in 2002

A 19 March 2002 DHHS OHRP letter to the

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[53] Appendix B-306;
http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02l.pdf

[54] Appendix B-312;
http://www.hhs.gov/ohrp/detrm_letrs/oct01j.pdf

University of California at Los Angeles,[55] "reminded" UCLA investigators, at page 2, that "Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 and 46.117 stipulate that no investigator may involve a human subject in research unless the investigator has obtained and documented the legally effective informed consent of the subject." DHHS OPRS then gave the following additional direction, at page 3:

> HHS regulations at 45 CFR 46.111(a)(6) require that in order to approve research covered by the regulations, the IRB shall determine, when appropriate, that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects [...] specifically, that the subjects will be monitored weekly via clinical evaluation by the investigator to assess potential adverse effects.

It appears Respondent Researchers in this case also had no plan to look after Nadine, as they refused to attend to her despite the fact that her condition suggested a surgical emergency.[56]

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[55] Appendix B-311; http://www.hhs.gov/ohrp/detrm_letrs/YR02/mar02f.pdf

[56] Appendix B-394 (Excerpt from deposition of respondent David Cesario, M.D., describing Dr. Swedlow's refusal to come to the aid of Nadine.); Also, AOB 9.

h. Drs. Swerdlow and Shivkumar knew their legal obligations

Respondents Drs. Swerdlow and Shivkumar are experienced researchers. In their publication,[57] C. Swerdlow, MD; K. Shivkumar, MD, PhD; J. Zhang, MS, Determination of the Upper Limit of Vulnerability Using Implantable Cardioverter-Defibrillator Electrograms, *Circulation*. 2003;107:3028-3033, at page 3028, they acknowledge:

> Patients were candidates for this study if they had left pectoral implants of an ICD with a lead implanted at or near the right ventricular apex. **All gave written, informed consent according to a protocol approved by the Human Subjects Committee**. [Bolding added]

And, what was the reaction of these Respondent Researchers upon being sued? They (Regents, et. al.) claimed government immunity.

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[57] http://circ.ahajournals.org/cgi/reprint/107/24/3028

B. DISCUSSION

In this case, like most, the "devil is in the details." Like "connecting he dots," each claimed judicial error is described for the "role" it played in the California courts' avoiding confronting federal regulations at issue in this case.[58]

The issues which follow were presented to the California Court of Appeals. The first in Petitioner's Motion and Request for Judicial Notice,[59] as well as his Petition for Review in the California Supreme Court.[60] The remainder, variously in the AOB, ARB, and in the Petition for Rehearing. Petitioner argued, in his Petition for Rehearing that these decisions and others, were the result of arbitrary adjudication and deprived hin of his constitutional due process rights. (*Ponte V. Real* 105 S.Ct. 2192 [471 U.S. 491] (1985); *People v. Ramirez* 25 Cal.3d 260, 268 [599 P.2d 622; 158 Cal.Rptr. 316] (1979); *Hernandez v. Department of Motor Vehicles* 30 Cal. 3d 70 [177 Cal. Rptr. 566, 634 P.2d 917 (1981) at p. 81 fn 12; U.S. Constitution, 5th and 14th Amendments; California Constitution, article I, § 15, cl. 7).

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[58] Appendix B-20 - B-40 (SAC §§44-84: describing protection of human subjects in medical device experimentation under the FDCA ("FDCA Protections") as applied to the facts alleged.)

[59] Appendix B-251 - B-342.

[60] APFR 20-23; SPFR 7-15.

1. This Court should grant review to determine whether liability for injury suffered from a surreptitious human subject experimentation protocol should be evaluated the same as if it resulted from medical treatment

By far the greatest number of the allegations in this litigation describe how Nadine was subjected to a surreptitious medical device evaluation experiment, one that the Respondent Researchers in this case themselves described to this Petitioner.

In a law review by E. Haavi Morreim, Medical Research Litigation And Malpractice Tort Doctrines: Courts on a Learning Curve, 4 *Hous. J. Health L & Pol'y* (2003),[61, 62] the author points out, at p. 26, that:

> [...] the bare fact that a physician has performed an intervention, or that it required some professional knowledge or skill, does not mean that intervention was medical practice.

Medical practice is premised on "standards of care," while, according to Morreim, at page 17,

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[61] Note that this manuscript was submitted, in its entirety, to the Court of Appeal with the "Motion and Request for Judicial Notice" CD (See Appendix B-251).

[62] Petitioner believes that this treatise is so well researched and conceived, it could serve as a basis for guiding the review of this case, given that it addresses matters of consent, ghost surgery and medical experimentation, all of which are issues in the present litigation.

> If the activity is designed "'to test an hypothesis, permit conclusions to be drawn,' and thereby to develop or contribute to generalizable knowledge, it is research." [Footnote]

Likewise, the court in *Spenceley v. M.D. Anderson Cancer Ctr.*, 938 F. Supp. 398, 398 (S.D. Tex. 1996), says medical and human subject research "is not standard; it is speculation, approximation, and inquiry."

Morreim, distinguishes the issue of "research" from "treatment."

First, the author points out, at page 17:

> If the activity is designed "'to test an hypothesis, permit conclusions to be drawn,' and thereby to develop or contribute to generalizable knowledge, it is research." [Footnote]

And at page 18-19:

> [...] it is not the goal of any research protocol to benefit any specified individual. Rather, it is to learn information. Benefit to any given individual is thus by good fortune, not by design, even if it happens that many individuals in that study benefit.

On page 18, footnote 94, in Jay Katz, Human Experimentation and Human Rights, 38 St. Louis U. L.J. 7, 14-15, 34 (1993) at page 25, Katz writes:

> Respect for the subjects' human rights dictates that they know that the decision to participate in research entails making a gift for the sake of others.

Nadine went to Drs. Swerdlow and Shivkumar for medical treatment. She didn't engage their services to make "a gift for the sake of others," including the training Dr. Cesario. Some examples of treatment distinguished from research follow.

Barrett v. United States 689 F.2d 324, 329 (2nd Cir. 1982), a psychiatric patient died after being given experimental mescaline without his knowledge or consent. The court observed that "[t]he gravamen of the FTCA claim [...] was not medical incompetence, but the fact that he [the decedent] was used as a human guinea pig."

In *Anderson v. George H. Lanier Memorial Hosp.* 982 F.2d 1513, 1519 (11th Cir. 1993), where patients unknowingly received an experimental intraocular lens (IOL) implant, the court held that "their claim is that they were never put on notice that they were the subjects of research. . . . Under the ruse of removing cataracts, Dr. Torsch may have committed fraud on these appellants when he inserted experimental IOLs in their eyes."

Morreim collects these thoughts and summarizes them at page 64:

> While medical practice seeks to benefit the individual patient, research seeks generalizable scientific knowledge via

> activities in accordance with a protocol. Therefore, when patients are subjected to research without their knowledge or consent, the investigator has covertly made a profound change of goals. Whereas the patient believes his personal welfare is the primary goal, the real goal is now to benefit society by following the protocol, even sometimes contrary to the patient's best interest.
>
> At the same time, the physician has also shifted his relationship with the patient from a fiduciary physician- patient relationship to a nonfiduciary investigator-subject connection.

For at least 122 years, at least since *Mugler v. Kansas*, 123 U.S. 623, 660-661 (1887), the Due Process Clause of the 14th Amendment to the U.S. Constitution has been understood to contain a substantive component, one "barring certain government actions regardless of the fairness of the procedures used to implement them." *Daniels v. Williams*, 474 U.S. 327, 331 (1986). In that context then, there is no rational government interest in cloaking human subject experimentation whose end-and-aim is "speculation, approximation, and inquiry," with the less stringent procedural framework accorded causes arising from the practice of medicine in which standards of care have been established.

As will now be illustrated, the failure of the California Courts' to evaluate the facts of this case in its

proper regulatory framework[63] deprived this Petitioner of his substantive and procedural due process rights under the 14th Amendment and his right to a fair trial under the 5th Amendment to the U.S. Constitution.

2. This Court should grant review to determine whether a motion for summary judgement can be granted when the moving party's own evidence establishes that the patient did not consent to the procedure performed and that the true purpose of the switch may have disguised a human subject experiment

A California court may not grant summary judgment sua sponte or solely on the basis of argument. (*Scheiding v. Dinwiddie Construction Co.* 69 Cal.App.4th 64, 75 (1999).) A defendant seeking summary adjudication must present evidence demonstrating an element of the plaintiff's cause of action cannot be established (*Aguilar v. Atlantic Richfield Co.*, 25 Cal.4th 826, 854 , 853-855 (2001)).

The Opinion, at section B,[64] takes great pains to discuss issues regarding standard of care. However, standard of care is not implicated in this case, because there was no consent to the procedure performed. The Opinion acknowledged this, but then held that it was the burden of the non-moving party, this Petitioner, to resolve the distinction.

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[63] FDCA Protections, op. cit. Appendix B-20

[64] Appendix A-43 - A-48.

This issue is introduced by the statement at Opinion Page 12:[65]

> although the LEPVI technique may differ from the "the wide area circumferential" technique, the extent of the difference, if any, must be established by the testimony of a qualified physician. Both of the UCLA defendants' physician experts opined the doctors used an appropriate technique to ablate Nadine's heart and properly performed the procedure.

But, that duty lies with the moving party. Normally, the presence of a material factual dispute will defeat a motion for summary judgment. (*Banks v. Dominican College* 35 Cal.App.4th 1545, 1551 (1995).) And, the California Supreme Court established that *any medical procedure* performed without the patient's consent is a battery irrespective of the skill or care used. (*Thor v. Superior Court* 5 Cal.4th 725, 735 [21 Cal.Rptr.2d 357; 855 P.2d 375] (1993)) That evidence showed Nadine did not consent to the procedure performed is enough to defeat Respondent Researchers' summary judgments .[66]

It should be noted that "[t]he decisions of [the California Supreme] [Court] are binding upon and must be followed by all the state courts of California." (*Auto Equity Sales, Inc. v. Superior Court* 57 Cal. 2d 450, 455

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[65] Appendix A-47.

[66] ARB 11, 39.

[20 Cal. Rptr. 321, 369 P.2d 937] (1962)) But, the Court of Appeal has clearly disregarded that holding in its Opinion which is diametrically opposed to *Thor*.

But, why the procedure "bait and switch? The answer to this question may be found in "Research disguised as 'standard of care' at UCSF in 2003," at page 18, *supra*, as well as *Anderson v. George H. Lanier Memorial Hosp.*, *supra*, 982 F.2d at 1519, where researchers disguised their human subject experiments as "treatment." Indeed, this issue was placed before the Court of Appeals in the AOB:

> Nadine was subjected to a procedure "bait and switch" in which a Wide Area Circumferential procedure was substituted, so that UCLA Respondents could use her surgery as a pretext to conduct a speculative medical experiment, without Nadine's knowledge or consent. (AOB:41)

Lastly, the Opinion, at pages 12, states:

> Plaintiff is not a physician and is not qualified to opine on whether the UCLA defendants met the applicable standard of care in performing the cardiac ablation or whether their actions caused Nadine's death.

But, in his declaration, this Petitioner-Appellant recounts *not medical incompetence*, but that *Nadine was used, without her knowledge or consent, as*

a human guinea pig.[67] Moreover, a prima facie case of battery does not require expert opinion as to a professional standard of care; rather, the patient must demonstrate only a failure to give informed consent and a mere touching absent such consent. (*Perry v. Shaw*, 88 Cal.App.4th 658, 663 (2001)) Ironically, it is Respondent Researchers themselves who proved that Nadine did not consent to the procedure that was performed.[68]

Here is exemplified how the medical malpractice paradigm distorts the view of surreptitious human subject experimentation. Because HSE "is not standard; it is speculation, approximation, and inquiry." The only "standard" is, in this case, the FDA regulations which govern medical device studies.

The Opinion's holdings on this issue are entirely arbitrary and raises due process concerns[69] that call for this Court's examination of its relationship to the medical experimentation to which Nadine was subjected.

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[67] Valer's Declaration, op. cit.

[68] Dr. Packer identified the procedure performed on Nadine as a "Pappone Technique," (Appendix B-177), while Nadine's consent was to the LEPVI (Swerdlow Letter, op. cit. Appendix B-169); ARB 38-40.

[69] APFR 22-26, 28.

3. This Court should grant review to determine whether the trial court's refusal to allow counsel to be heard on evidentiary issues at the summary judgment hearing deprived Petitioner of his Constitutional due process guarantees and improperly excluded admissions of experimentation

During the hearing on the summary judgment motions at issue in this petition, Petitioner's attorney asked to address evidentiary issues.[70] The lower court responded:

> "I don't argue evidentiary objections. . . I just go ahead and read the paperwork, look at the objections and rule on them, so – because otherwise, we have speaking objections, and I don't do that." (AOB:47)

a. The CCP § 2015.5 objection

The declaration of Dr. Andrea Natale submitted to evidence by the Regents, et. al., was incompetent.[71] Obviously, the only time that it could be effectively challenged was at the hearing on the summary judgment motion.

This issue was raised on Appeal. The Opinion

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[70] The entire text of briefs placed before the California Courts on this issue is reproduced at Appendix A-105 - A-122.

[71] See Appendix A-42, footnote 5 of the Opinion for explanation of this California Code of Civil Procedure § 2015.5).

states at page 10-11,[72] that:

> Plaintiff, however, never filed any objections to Natale's declaration, and therefore waived the point [Citation] (See, e.g., *Rader v. Thrasher* (1972) 22 Cal.App.3d 883, 886.) [73]

Petitioner filed a Petition for Rehearing pointing out that California's summary judgment statute provides for no such restriction. The right to make objections orally, "at the hearing," is statutorily conferred. (CCP § 437c (b)(5)) Objections to evidence may be either filed or made orally at the hearing on the motion; See also *City of Long Beach v. Farmers & Merchants Bank of Long Beach* (2000) 81 Cal.App.4th 780, 783 [81 Cal.App.4th 780; 97 Cal.Rptr.2d 140])

On 22 December 2008, the Court of Appeal modified its opinion. In the Modified Opinion, the Court deletes the above-quoted sentence and its citation to *Rader*. The Modification then engages in a lengthy speculation of possibilities regarding the myriad of ways Plaintiff counsel might have raised "reviewing court approved" objections to the Natale declaration.

However, the "analysis" is entirely arbitrary and based on no legal authority. (*Ponte V. Real*, 471 U.S. 491, *supra*; *Traxler v Thompson* 4 Cal App 3d 278, 288 [84 Cal Rptr 211] (1970) [a legal inference cannot

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[72] Appendix A-41 - A-44.

[73] In Findlaw (www.Findlaw.com), the actual cite is to page 889, not 886)

flow from the nonexistence of a fact; [...]. An inference may not be based on suspicion alone, or on imagination, speculation, supposition, surmise, conjecture or guesswork.]).

The M-Opinion goes on to state that "Significantly, plaintiff's counsel requested the opportunity to *argue* objections, and never informed the court he wished to make new objections."

In the "spirit of parsing," it would not have mattered how counsel introduced his desire to speak or "object" to the evidence. The trial court wasn't going to allow any "speaking objections" of any kind by Plaintiff counsel. (See California Civil Code §3526: No man is responsible for that which no man can control.)

Consequently, the ruling allowing the Natale Declaration cannot withstand Constitutional scrutiny. Both the Opinion and Modification violate Petitioner-Appellant's due process rights, guaranteed by the U. S. Constitutions, when it arbitrarily ruled that a party will only be heard at the pleasure of the courts.

Petitioner raised and addressed the matter of Due Process Right violations in this matter in all briefs and asserts that it cannot withstand constitutional scrutiny.[74]

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[74] Appendix A-105 - A-122 contains the text from Petitioners briefs on this issue showing it was pursued from the moment it arose. (AOB:47-49, ARB:44-45, especially APFR:18-22, SPFR:27-30).

b. Other evidentiary issues

In addition, left unanswered, the myriad of other evidentiary issues raised in the AOB, such as the summary exclusion from evidence of all exhibits and witness testimony which in any way even so much as mentioned the surreptitious medical experiment to which Nadine was subjected.[75] For example, excluded was paragraph 1 of Valer's declaration which begins: "I am a personal witness to all that I describe," as well as all paragraphs in which Valer recounts his and Nadine's conversations with Drs. Swerdlow and Shivkumar about agreements made regarding Nadine's treatment and Valer's conversations with these physicians regrding the medical experiment to which Nadine was subjected. Also excluded were Valer and Nadine's e-mails communications with Drs. Swerdlow and Shivkumar as well as the publications which announced the experimental research, some of which are reproduced in Appendix B.[76]

All of the testimony and the exhibits not only confirmed the truth of the allegations made in the SAC, but were also proof that the FDA regulations governing human experimentation had not been followed.

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[75] Appendix A-24, bottom, discussing evidence.

[76] Swerdlow Letter, op. cit. Appendix B-165; Appendix B-219 (18 September 2003 email between Dr. Swerdlow and Nadine discussing how Drs. Swerdlow and Shivkumar work as a team); Appendix B-225 (1 December 2003 email between Dr. Swerdlow and Nadine re: choice of surgical team); Valer's Emails, op. cit. Appendix B-233; Cesario, et. al. op. cit. Petition Appendix B-245; Conte, op. cit. Petition Appendix B-247.

It should be noted that the Court of Appeal made much of these evidentiary rulings by stating " Plaintiff provided no competent evidence [...]"[77] Yet never addressed these issues as they were raised on appeal.[78, 79]

Lastly, the hearing required by the Due Process Clause must be "meaningful," *Armstrong v. Manzo*, 380 U.S. 545, [402 U.S. 535, 542] 552 (1965), and "appropriate to the nature of the case." *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306 (1950), at 313. A hearing which excludes consideration of an element essential to the decision does not meet this standard. (*Bell v. Burson*, 402 U.S. 535, 541-542 (1971) This petitioner believes that the denial of the right to be heard at the MSJ hearing as well as the systematic exclusion of admissions of the human subject experimentation, and the failure of the courts deciding this case to adhere to the federal regulations governing that conduct should rise to the level of constitutional scrutiny.

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[77] Appendix A-1.

[78] Appendix A-109 - A-113 (Text from the portion of the AOB arguing that the disputed items of evidence were wrongly excluded.)

[79] However, the Opinion at page 16 (Appendix A-52), cites to the text of Valer's Declaration, ¶27, which was excluded from evidence by the trial court (MSJ Ruling, Appendix A-27, top of page).

4. This Court should grant review to determine whether the California courts' failure to cite to the specific facts of the complaint on the issue of medical experimentation in the Motions for Summary Judgment deprived Petitioner of his Constitutional due process guarantees and acted to exclude issues of human subject experimentation from consideration

California incorporates most of the federal scheme in its Summary Judgment process. A summary judgment is reviewed on appeal by applying the same three-step analysis required of the trial court. Moreover, this is a statutory duty. (CCP §437c; *Aarts Productions, Inc. v. Crocker National Bank* (1986) 179 Cal.App.3d 1061, 1064 [225 Cal.Rptr. 203]) First, the issues framed by the pleadings must be identified, since it is these allegations to which the motion must respond. (*Sadlier v. Superior Court* (1986) 184 Cal.App.3d 1050, 1055.)

Neither Respondent Researchers' Motions for Summary Judgment nor the Opinion cite to the facts of the complaint.[80] Under these circumstances, since Respondent Researchers never addressed the issues framed by the Second Amended Complaint, the burden of proof never shifted to Appellant-plaintiff, no matter the argument and/or evidence presented in support of the motion.

First, approximately 20 pages of narrative regarding human subject experimentation statutes and

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[80] AOB:62-64; also ARB:34-37.

regulations were ignored -- from the outset.[81] If a medical device used experimentally was to be considered at all, it could not be considered outside the FDA regulatory framework.

Next, the Opinion,[82] states that "use of [sic] and esophageal temperature probe, was not "experimental or investigational" at the time of the operation." There is no issue of a nondescript temperature probe utilized for some unspecified purpose in the SAC. The "experimentation issue" framed by the SAC is whether the Vital Temp model 1101-18Fr Series 400 Esophageal Stethoscope, manufactured by Vital Signs, Inc.[83] can do the job of an atrio-esophageal fistula prevention monitor.[84] In the end, the answer turned out to be: no, it can't.[85]

Lastly, the Second Amended Complaint states that Nadine hired Drs. Swerdlow and Shivkumar to *personally* perform her procedure.[86] The Opinion makes no mention of this essential fact. Consequently its holdings on Dr. Cesario's participation in Nadine's

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[81] FDCA Protections, op. cit. Appendix B-20 - B-40

[82] A-58, 59.

[83] See e.g. Appendix B-7 (SAC §12); B-23 (SAC §49).

[84] Appendix B-79 - B-99 (SAC §§155-202: The Experimental Form of the Ablation Procedure Revealed); AOB:62

[85] Appendix B-403 - B-407 (Excerpts from the ARB 32-34,Section IV: Expert Witness Ipse Dixitisms).

[86] See e.g. Appendix B-19 (SAC §40); B-70 (SAC §130); B-73 (SAC §139)

procedure are entirely arbitrary.

The Opinion does not address these issues, as they are framed by the SAC. Consequently, the failure of the Opinion to cite to and evaluate the specific allegations of the complaint deprived Petitioner his Constitutionally prote ed statutorily mandated due process right to a fair trial and freedom from arbitrary adjudication.

5. This Court should grant review to determine whether the Constitutional right to personal autonomy entitles a patient to specifically choose those who will be permitted to exclusively perform medical procedures on them

On these closely related issues,[87] the Opinion states in pertinent part (at page 20): "the facts did not demonstrate Swerdlow had a legal obligation to prevent Shivkumar from leaving the operating room." Once again, the Opinion fails to cite to the specific allegations of the SAC. Nothing in the SAC claimed such a duty. Instead, SAC §252 (1.CT.135) alleges that:

> These actions were entirely alien to and beyond the scope of NADINE's objectively reasonable expectations with respect to her conditional consent. Therefore, Nadine's consent to the treatment was vitiated and annulled when the "surgical team" of Drs. Swerdlow and Shivkumar did not perform

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[87] APFR:29-31.

the ablation procedure as was promised and agreed.

When Dr. Shivkumar left the operating room, Nadine's consent left with him, because Drs. Swerdlow and Shivkmar had agreed to *personally perform* Nadine's procedure.[88] No personal performance by, Drs. Swerdlow and Shivkumar, simply means "no consent."

The Opinion goes on: "Plaintiff does not allege the doctors explained to Nadine how they would work as a team."[89] The Opinion placed this Petitioner-Appellant-Plaintiff in an impossible position. Nadine made such an attempt. In an e-mail dated 18 September 2003, submitted with Petitioner-Plaintiff's opposition to the summary judgment motions, Dr. Swerdlow replied to her inquiry: "Each of us is qualified to do all parts of the procedure. The Court of Appeals had this document before them and can be assumed to know these facts. What we do when we work together varies from case to case." [90] (See California Civil Code §3526: No man is responsible for that which no man can control.)[91]

Lastly, the choice of operating surgeons is a highly personal one. In such a case, both state and federal constitutional protections involving rights

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[88] Ibid.

[89] Appendix A-56.

[90] Appendix-B-219 - B-223 (18 September 2003 email between Dr. Swerdlow and Nadine discussing how Drs. Swerdlow and Shivkumar work as a team).

[91] APFR 29-31

granted under the concept of personal liberty embodied in the Fourteenth Amendment's Due Process Clause; or in personal privacy said to be protected by the Bill of Rights or its penumbras or among those rights reserved to the people by the Ninth Amendment, as well as interests in autonomy protected under article I, section 1, of the California Constitution, precludes a state-mandated imposition as to who a patient could allow to perform surgery. (See generally *Roe et al. v. Wade, supra*, 93 S.Ct. 705)

A person has a constitutionally protected interest in refusing unwanted medical treatment. (*Cruzan v. Director, Mo. Health Dept.* (1990) 497 U.S. 261, --- [111 L.Ed.2d 224, 241; 110 S.Ct. 2841, ----]; *Bouvia v. Superior Court* (1986) 179 Cal.App.3d 1127 [225 Cal.Rptr. 297])[92] "A battery is a violation of an individual's interest in freedom from intentional unlawful, harmful or offensive unconsented contacts with his or her person. [Citation.]" (*Rains v. Superior Court* (1984) 150 Cal.App.3d 933, 938.) There is no "standard of care" (Opinion, page 23)[93] which would relieve a "ghost surgeon" from liability for battery. All that is required is a touching absent consent.[94]

Absent citation to the issues as they are actually framed by the complaint, both the trial court's ruling and the Opinion are entirely arbitrary and has deprived Appellant of a fair trial and due process protection

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[92] SPFR brief pp.18-19.

[93] Appendix A-60.

[94] APFR brief at pp.32, 33.

against arbitrary adjudications. (*Ponte V. Real, supra*, 471 U.S. 491; U.S. Constitution, 5th and 14th Amendments)

CONCLUSION: MEDICAL RESEARCH OR MEDICAL PRACTICE?

The Fourteenth Amendment of the United States Constitution provides that "[n]o State shall . . . deprive any person of life, liberty, or property, without due process of law." (U.S. Const. amend. XIV, § 1)

However, this is a hollow promise when Nadine was "snatched" (even if figuratively) from her hospital bed and conscripted as an object of training and experimentation -- then after the injury that was caused her became apparent, she was literally discarded, and left to die.

Dr. Benjamin Rush, signer of the Declaration of Independence once said:[95]

> Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an underground dictatorship . . . To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic and have no place in a republic. The Constitution of this republic should

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[95] http://www.distance-healer.com/28.html

make special privilege for medical freedom as well as religious freedom.

For Valer and Nadine Searea (and too many others), these fears are their reality.

The "Respondent Researchers" in this case were able to publish and present their covert human subject experimentation with no fear whatsoever of being held accountable for the life they so casually extinguished.

In his dissent in *Washington v. Harper*, 494 U.S. 210, 237, 110 S. Ct. 1028, 1045, 108 L. Ed. 2d 178, 208 (1990), Justice Stevens of this court commented (at footnote 2):

> "[T]he Constitution's promise of due process of law guarantees at least compensation for violations of the principle stated by the Nuremberg Military Tribunals `that the "voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts[.]"'); ([T]he Fourteenth Amendment protects the `freedom to care for one's health and person[.]')" Id. at 238, 110 S. Ct. at 1045, 108 L. Ed. 2d at 209 (citation and emphasis omitted).

That freedom of which Justice Stevens spoke was extinguished by not only the Respondent Researchers in their mistreatment of Nadine, but the court decisions which went so far to remove from view the federally regulated human subject experimentation

which is the gravamen of this litigation, and about which Respondent Researchers are so free to boast.

It is for that reason this court should grant review to this case so that the Constitution's protections can be something more than a footnote of wishful thinking to those who are or could be confronted with the circumstances depicted in this Petition.

Dated: 24 July 2009

Respectfully submitted,
/s

Valer V. Secarea, Jr
Petitioner, Appellant and Plaintiff
In Propria Persona

APPENDIX A

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Trial Court Rulings on Demurrers

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[Original: Page 1]

SUPERIOR COURT OF CALIFORNIA
COUNTY OF ORANGE
MINUTE ORDER
14-MAR-2006

Dept: C11 Central Justice Center
Convened at: 2:00:00

Judge/Comm: William M Monroe
Clerk: Denise Drehsen
Bailiff: Debora Vandor
Reporter: Lisa Dunmore CSR 9571

Court Type: Civil

Court Category: Malpractice-Medical

Case Number: 05CC10019

Case Title: Secarea vs Regents of the University of California

Doct Seq No: 84

Event: 601 Discovery-Interrogatories
Filing Party: Vital Signs, Inc.
602 Discovery-demand to produce/In
Filing Party: Vital Signs, Inc.
637 Motion to Dismiss
Filing Party: Regents of the University of California

683 Demurrer to amended complaint
Filing Party: Regents of the University of California
654 Motion to Strike
Filing Party: Regents of the University of California
683 Demurrer to amended complaint
Filing Party: Swerdlow, Charles
632 Motion re: Joinder
Filing Party: Regents of the University of California
632 Motion re Joinder
Filing Party: Swerdlow, Charles

Appearances:

[Original: Page 2]

Plaintiff Attorney	Rocket III, Thomas E. - Law Offices of
Defendant Attorney	Maranga & Morgenstern by John F Peterson

The following is the court's tentative ruling as posted on the internet this date.

Motion to Compel Responses to Form Interrogatories and Motion to Compel Production of Documents filed by Vital Signs, Inc. off calendar pursuant to telephonic request of moving party. Moving Party to give notice.

The following is the Court's tentative ruling as posted on the Internet this date.

Motion filed by Defendants Regents of UCI, Kalyanam Shivkumar, M.D., & David Cesario, M.D.

The Regents of UCI and their physicians, Drs Shivkumar and Cesario, move to dismiss the 9th and 10th Causes of Action for Products Liability, strict liability and negligence on the ground that the court previously sustained Defendants' Demurrer on these causes of action without leave to amend, yet Plaintiff has re-pled them in his 2nd Amended Complaint.

Given the Court's ruling in the minute order, and Plaintiff's own mistake in giving improper notice of the ruling, Plaintiff is not entitled to amend these causes of action.

The Court in its discretion under its authority provided in CCP § 436(b) finds that the Plaintiff's 2nd Amended Complaint fails to conform to the two causes of action for products liability were sustained without leave to amend. Plaintiff's notice of ruling of 12-29-05 misstates the Court's ruling on the Demurrer. The court orders the 9th and 10th Causes of Action for Products Liability are stricken from the 2nd Amended Complaint, based on its prior ruling.

Demurrer to 2nd Amended Complaint

Motion to Strike portions of 2nd Amended Complaint

Demurrer to 2nd Amended Complaint

Joinder to Swerdlow's Demurrer

Joinder to Regent's Motion to Strike

The allegations of the 2nd - 10th Causes of Action and the prayer for these causes of action seek no further damages distinct from the damages sought in the 1st and 11th Causes of Action. Plaintiff has not sought within the 3rd - 8th Causes of Action, any other recoverable damages as a survival Cause of Action, then what he is already requesting in his 11th Cause of Action. Pleading the 2nd - 8th Causes of Action are therefore pointless.

[Original: Page 3]

If plaintiff however, intends to plead an intention to amend the complaint for punitive damages pursuant to CCP § 425.13, there would be a basis for the claims. Plaintiff has made no such allegation, nor pled facts indicative of supporting a future claim. The appropriate remedy seems to be to dispose of them through judgment on the pleadings or an motion for summary judgment.

2nd & 3rd causes of action for informed consent: plaintiff does not sufficiently allege that any of the acts of defendant were unlawful or illegal. He fails to state lack of information consent on those grounds taking the allegations that defendant was engaged in an experimental form of the procedure as true for the demurrer, it does not necessarily indicate a duty on

defendant's part to disclose exactly how he is doing the procedure. These are areas of the technical procedure that are left to the discretion of the physician. Courts have declined to define exactly what should be disclosed, but have left it up to a case-by-case analysis.

Plaintiff admits that Defendant and decedents discussion of the risks of the procedure decedent was provided with published literature, and again discussed the risks and complications prior to surgery. Plaintiff clearly understood the possibility of death or serious injury. Plaintiff and decedent discussed the risks of the procedure. Decedent was provided with published literature, and against discussed the risks and complications prior to surgery. Plaintiff and decedent also did research and searching before undergoing the procedure.

A mini-course in medical science is not required. Knowing that she can die, not how she may die is what is important for the decedent to have made her decision. However, Plaintiff has sufficiently raised allegation in the 2nd Cause of Action that Defendant was involved in a research project pertaining to the procedure decedent underwent. These issues were material and specific topics of his ongoing research, to give rise to a claim that Defendant had a duty to disclose his personal interests in his research project which was unrelated to decedent's health.

The 3rd Cause Action for Abandonment is unsupported by the pleaded facts as to Defendant Swerdlow.

Plaintiff's argument that because she consented only to the team, Defendant Swerdlow should somehow be liable based on lack of informed consent for Defendant Shivkumar leaving the operating room for a period of time, is an unsupported strain of logic. Plaintiff has failed to allege a duty and breach of a duty on Defendant Swerdlow's part by not stopping co-defendant from leaving the operating room. The facts do not plead abandonment of the patient.

4th and 5th Causes of Action for Battery: since Plaintiff fails to allege a cause of action for lack of informed consent against Defendant Swerdlow on the abandonment theory, there is no basis for battery on this theory as well. Plaintiff has not presented sufficient facts to support the cardiac ablation procedure decedent underwent was unlawful.

The case of *Nelson v Gaunt* (1981) 125 Cal. App. 3rd 623, is not on point, in that the Defendant doctor in that case was using silicon, an illegal substance. Here, Plaintiff allegations do not claim the vital signs probe was an illegal instrument, and that Defendants intentionally misrepresented their ability to use the probe.

Plaintiff fails to state that the doctors, who agreed to perform as a team, actually failed to perform as a team, simply because one of the two doctors left the operating room for a period of time. *Ashcroft v. King* (1991) 228 Cal. App. 3d 604 is inapposite to Plaintiff's argument. Plaintiff's condition on consent was that the doctors

acted as a team. No where in the complaint has Plaintiff alleged sufficient fact that they did not act as a team.

[Original: Page 4]

Involving another surgeon to assist during surgery did not negate that the two doctors were a team, nor does it establish that they were not continuing to work together for the benefit of decedent.

The allegations fall short of showing intent to deviate from the procedure and conditions decedent consented to. The facts as alleged sound in negligence and not in intentional misconduct to constitute a tort for battery. 6th and 7th Causes of Action for Fraud: Plaintiff has added additional allegations, with many inflammatory adjectives but he has failed to substantiate the essence of the claim with facts showing actionable fraud by Defendants. Though the 2nd Amended Complaint is rather intriguing and fascinating, but it is more hyperbole than fact.

The intention/scienter is simply missing from the nature of the circumstances. Plaintiff has not sufficiently pled that the surgery was actually experimental. The fraud is also based on the violation of the "team". Plaintiff has failed to allege that an actual violation of this alleged "team promise" occurred. Plaintiff admits in her complaint that other physicians, associates and staff personnel would be present and assisting the surgeons during the procedure. This admission takes the last puff of wind out of fraud sails.

Public employees are immune from liability for an injury caused by their employees' negligent or intentional misrepresentations. Plaintiff's allegations are devoid of showing ill will or the desire to do harm for the satisfaction of doing it.

Plaintiff has no claim for fraud. We have read these earlier. Plaintiff rightly believes he had a moral obligation to protect his wife, however, that gives him no legal rights to maintain a cause of action for fraud where he was not a party to the acts, not injured by the fraud, and no facts for fraud exist.

8th Cause of Action for Negligence per se: Plaintiff was given the opportunity to amend the complaint to state any statutory violations by the government defendants. Plaintiff continues to fail to plead the requisite statute necessary to maintain a cause of action.

9th and 10th Cause of Action for Products Liability: these causes of action were previously sustained without leave to amend. Plaintiff prepared an improper notice of ruling. The inclusion of UCLA as being a supplier because it has a pharmacy doesn't fly in light of the overwhelming case authority which has refused to place liability on medical providers for products liability.

Motion to Strike: the issues raised in the motion to strike which were necessarily addressed by the Demurrer are moot, based on the sustaining of the Demurrer as to all causes of action in question.

All allegations for oppressive, fraudulent, malicious, wanton reckless conduct in pages 58

[Original: Page 5]

through 63, not removed by the Demurrer are stricken as Plaintiff has failed to show through factual allegations, the conduct was despicable, and rises to any of the buzz words.

Plaintiff was told to clean up his complaint to reflect the proper awardable damages for the appropriate cause of action. Plaintiff failed to do this in the 2nd Amended Complaint.

Plaintiff claims he is not seeking economic damages under the wrongful death cause of action; however, his prayer is not conformity with the law as even he recites it. General damages appear that he is seeking to recover pain and suffering of the decedent.

Only economic damages sustained by the decedent before death are recoverable damages in a survival action. Future economic damages are not recoverable. Once dead, the decedent cannot in any practical way be compensated for her injuries or pain and suffering.

The prayer for prejudgment interest against the Government Defendants and its employees is stricken as cc § 3291 clearly prohibits the recovery of interest from these Defendants.

The Court's tentative ruling is as follows: Defendants', the Regents of [sic] UCI, Kalyanam Shivkumar, M.D., and David Cesario, M.D., Demurrer to the 4th through 8th Causes of Action in the 2nd Amended Complaint is sustained without leave to amend on the ground that Plaintiff is unable to cure the defects in his pleadings, which amount to fatal deficits in the alleged causes of action. The Demurrer as to the 9th and 10th Causes of Action is moot based on the Court's prior order on 12/20/05, sustaining those causes of action without leave to amend, on the basis that Plaintiff cannot maintain products liability claims against Defendants who are health care providers.

Defendant, Charles Swerdlow, M.D.'s General Demurrer to plaintiff's complaint is overruled. Defendant's Special Demurrer to the 2nd Cause of Action for lack of informed consent is overruled. The Demurrer to the 3rd, 4th, 5th, 6th, 7th and 8th Causes of Action are sustained without leave to amend for the reasons stated above. The Demurrer to the 9th and 10th Causes of Action are moot as stated above.

The issues raised in the motion to strike which were necessarily addressed by the Demurrer are moot. All allegations for oppressive, fraudulent, malicious, wanton reckless conduct in pages 58 through 63, not removed by the Demurrer are stricken as plaintiff has failed to show through factual allegations, the conduct of Defendants was despicable, and rises to the level any of the pled words.

Plaintiff was previously ordered to strike the improper damages allegations and prayer relief requested for improper wrongful death damages alleged and improper survival damages alleged. Plaintiff failed to follow this court's order. Counsel, you proceed at your own peril if you persist.

The 1st Cause of Action for Wrongful Death: again pleads damages for loss of earnings and future earnings. He is entitled to pecuniary loss for loss of comfort, loss of society and loss of support. By pleading for general damages, it appears that he is seeking to recover pain and

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suffering of the decedent, which is not recoverable.

Yet in the remaining causes of action not disposed of by Demurrer, Plaintiff pleads for economic damages not sustained by the Defendant.

No recovery is allowed for general or compensatory damages in a survival action. All references to such damages in the remaining survival causes of action are ordered stricken from the 2nd Amended Complaint. The prayer for prejudgment interest against the government defendant regents and its doctor employees is stricken as CC § 3291 clearly prohibits such recovery. Plaintiff must amend to seek prejudgment interest against defendant Swerdlow only or leave the prayer out.

All Counsel submitted on the Court's tentative ruling as posted on the Internet this date. Defendants to give notice of ruling on their respective Demurrers and Motions.

Entered: 03/14/06

Trial Court Rulings on Motions for Summary Judgment

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[Original: Page 1]

SUPERIOR COURT OF CALIFORNIA
COUNTY OF ORANGE
MINUTE ORDER
08-AUG-2006

Dept: C11 Central Justice Center
Convened at: 2:00:00

Judge/Comm: William M Monroe
Clerk: Denise Drehsen
Bailiff: Debora Vandor
Reporter: Lisa Dunmore CSR 9571

Court Type: Civil

Court Category: Malpractice-Medical

Case Number: 05CC10019

Case Title: Secarea vs Regents of the University of California

Doct Seq No: 120

Event: 640 Motion for Summary Judgment/Ad
Filing Party: Irvine Regional Hospital and Medical Center
640 Motion for Summary Judgment/Ad
Filing Party: Regents of the University of California
640 Motion for Summary Judgment/Ad

Filing Party:	Swarzentruber, Richard
640	Motion for Summary Judgment/Ad
Filing Party:	Schwartz M.d., Alan c.
640	Motion for Summary Judgment/Ad
Filing Party:	Swerdlow, Charles

Appearances:

Plaintiff Attorney	Rocket III, Thomas E. - Law Offices of
Defendant Attorney	Taylor Blessey LLP by Raymond L. Blessey
Defendant Attorney	Carroll, Kelly, Trotter, Franzen & Mckenna by Dmitriy Cherepinskiy
Defendant Attorney	Maranga & Morgenstern by Patricia E. Ellyatt

The following is the court's tentative ruling as posted on the internet this date.

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Defendant Irvine Regional Hospital and Medical Center (Irvine) moves for summary judgment on plaintiff's complaint.

Plaintiff raises numerous idiosyncrasies with some of the lack of documentation by the nurses (mode of

arrival, who patient was accompanied by, who informed the emergency room of patient's condition, and even pain assessment, no coments under post intervention response, location of IV site and condition of [sic] ISTE Note re: oxygen use, and vomiting.) The majority of the "problems" even if violations in the standard of care as plaintiff's expert witness asserts (defendant's expert witness denies) were minor and do not create a triable issue of fact as material breaches in the standard of care. A few of the problems noted by plaintiff's expert witness, including the nurse's note of neurological assessment being within normal limits, lack of documenting O2 saturation and even a failure to document assessments during blocks of time may raise a triable issue as to standard of care, however, these violations fail to create a triable issue of fact as to causation.

The expert witness fails to identify how the "substandard" nursing care, or how the lack of communication with the emergency room physician more likely than not causes decedent's death. The fact that a breach in standard of care may have occurred does not automatically result in the cause of death in this case. Plaintiff's expert witness acknowledges that the emergency room physician knew the "critical information" and documented it in his emergency room summary.

The court doesn't have the discretion to deny summary judgment since the evidence discloses no triable issue as to any material fact.

The court finds that the expert opinion of plaintiff's expert is insufficient as a matter of law to rebut the burden met by defendant that to a reasonable medical probability no acts or omissions of defendant, caused or contributed to decedent's death and any of plaintiff's injuries. Motion for summary judgment is granted.

Defendants uci, Kalyanam Shivkumar, M.D., and David Cesario, M.D., move for summary judgment or in the alternatively for summary adjudication of issues on 1st, 2nd, 3rd and 11th causes of action pertaining to defendant in plaintiff's 2nd Amended Complaint.

The theory against the cardiologists, Dr. Shivkumar and Dr. Cesario

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and their employer, [sic] UCI, is the same as alleged against defendant Swerdlow.

As is the case with Dr. Swerdlow, plaintiff failed to present any expert witness declaration to address standard of care, and more importantly causation. Any breach in the standard of care must be the legal cause of the alleged injury.

Caustion is still a required element of the claim and expert testimony is necessary to prove that element. Plaintiff must show within a reasonable medical probability based upon expert witness opinion testimony that the defendants' conduct causes the

injury. Plaintiff's failure to provide expert opinion testimony on the standard of care and causation is fatal to h is action.

Defendant, Shivkumar and Cesario motion for summary judgment is granted.

Defendant Charles Swerdlow moves for summary judgment on plaintiff's 2nd Amended Complaint.

Separate statement of facts

1) Facts #1-8, 10-1 1: Undisputed.
2) Facts #9, 12-16: Undisputed.
3) Fact # 17: Undisputed.

The theory against the cardiologist, Dr. Swerdlow is that he failed to provide sufficient informed consent on four points: (1) decedent did not consent to the ablation procedure that was performed on her; (2) the risk of atrio-esophageal fistula was not disclosed to her; (3) decedent didn't consent to defendant Dr. Cesario's participation in her ablaiton procdure; and (4) an esophageal temperature monitoring experiment was performed on decedent as research without her informed consent.

Here, plaintiff admits that the decedent was informed by defendant of many serious risks and complication, including death that could result from the ablation procedure.

Plaintiff however contends that defendant filed to give informed consent because he did not disclose 1 specific risk to cardiac ablation- that of atrio-esophageal fistula. He claims the decedent would never have consented to the ablation procedure had this risk been told to her. Plaintiff then admits several paragraphs later in his declaration that decedent was in fact informed of the

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Exact risk of atrio-esophageal fistula assocaited with the transesophageal echocardiogram procedure she agreed to and did undergo. Whether decedent was injured or not during the transesophageal echocardiogram is not material to this issue, what is material is that decedent was advised of the risk of suffering an atrio-esophageal fistula as a result of undergoing at least one of the procedures she was contemplating to undergo, and she in fact consented to the procedure knowing that she could experience this result.

An objective test is used, i.e., what would a prudent person in the patient's position have decided if adequately informed of all significant perils. Since decedent accepted the risk of cardiac perfortion under both the transesophageal echocardiogram and the cardiac ablation, it is reasonable under the objective prudent person-test-to believe that if decedent -accepted-the risk of fistula once, that consent would not suddenly be withdrawn because the risk was also possible with [sic] cardiace ablation. There is no admissible evidence submitted by plaintiff that [sic]

decendent would not have submitted to the cardiac ablation procedure.

Plaintiff is not a medical doctor; he has no medical training, education or experience. His declaration is wholly insufficient to address the medical issues.

Defendant was not required to explain minor risks that were not likely to occur. Decedent's interest in information didn't require a lengthy polysyllabic discourse on all possible complications. Decedent was not entitled to a mini-course in medical science.

Defendant provided a declaration from Dr. Douglas Packer stating that the disclosures regarding the risks and complications of the procedure provided by dr. swerdlow to decedent complied with the applicable standard of care. Defendant's expert witness opines that the use of esophageal temperature probe was within the standard of care for defendant to use during the cardiac ablation. Plaintiff cites no authority that physician is compelled by a duty to disclose the type of tools, instruments and equipment he will use to accomplish the procedure which the patient is consenting to. The only dispute is over the technique used. This court previously ruled on plaintiff's 2nd Amended Complaint that there is not necessary a duty on defendant's part to disclose exactly how he is doing the procedure. These areas of technical procedure are left to the discretion of the physician.

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The burden of going forward with evidence of nondisclosure rests on the plaintiff.

Though a material disputed fact may be raised by plaintiff to create a triable issue whether decedent consented to another doctor actively participating in the case, the plaintiff cannot overcome summary judgment as a matter of law, because he failed again to submit an expert witness. Plaintiff doesn't set forth any facts to raise a triable issue how Dr. Swerdlow is responsible for Dr. Cesario assuming Dr. Shivkumar's role in the surgery. Plaintiff fails to submit the opinion of an expert witness stating that the decedent's death was to a reasonable probability caused by Dr. Cesario's participation in the surgery.

Defendant, Charles Swerdlow, M.D.'s motion for summary judgment is granted.

Motions filed by defendants Richard Swarzentruber, M.D. and Alan C. Swartz, M.D. are off calendar pursuant to telephonic request of moving parties.

The court made ruling on the following evidentiary objections brought by defendants regents of the 'university of california, dr..s shivkumar and cesario: as to defendants' objections to the declaration of valer v. secarea, jr. and these defendants' joinder to the following objections of co-counsel swerdlow to that declaration the court ruled as follows: a. paragraph 1 to 9 - sustained; b. paragraph 10 - overruled; c. paragraphs 11 to 16 - sustained; d. paragraph 18 - overruled; e.

paragraphs 19 to 21; f. paragraph 23 to 41- sustained; g. paragraph 43 - overruled; h. paragraph 44 - sustained; I. paragraph 45 - overruled; j. paragraph 46 to 47 - sustained; k. paragraph 48 - overruled; l. paragraphs 49 to 62 - sustained.

As to plaintiff's documentary exhibits 1 through 13, all objections are sustained.

Orders and judgments to be submitted to the court forthwith.

Moving parties to give notice. Entered: 8-8-06

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Opinion of the California Court of Appeals

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[Opinion Original: Page 1]

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FOURTH APPELLATE DISTRICT
DIVISION THREE

VALER V. SECAREA, JR.,
Plaintiff and Appellant,
v.
REGENTS OF THE UNIVERSITY OF CALIFORNIA et al.,
Defendants and Respondents.
G037651
(Super. Ct. No. 05CC10019)

O P I N I O N

Appeal from judgments of the Superior Court of Orange County, William M. Monroe, Judge. Affirmed in part, Reversed in part.

Valer V. Secarea, Jr., in pro. per., for Plaintiff and Appellant.

Taylor Blessey and Barbara M. Reardon for Defendant and Respondent Charles Swerdlow, M.D.

Carroll, Kelly, Trotter, Franzen & McKenna, Mark V. Franzen, Dmitriy Cherepinskiy and David P. Pruett for Defendant and Respondent Irvine Regional Hospital and Medical Center.

Maranga & Morgenstern, John F. Peterson; Greines, Martin, Stein & Richland, Martin Stein and Cynthia E. Tobisman for Defendants and Respondents

Regents of the University of California, Kalyanam Shivkumar, M.D., and David Cesario, M.D.

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Plaintiff Valer V. Secarea, Jr.'s, wife, Nadine, died from a rare complication associated with a catheter ablation procedure to mitigate her irregular heartbeat. Plaintiff sued defendants the Regents of the University of California (the Regents), Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow, M.D.[1] for medical malpractice and wrongful death, and other causes of action. Plaintiff alleges the doctors failed to inform Nadine of the risk of death from the particular surgical complication which took her life; performed a different procedure from the one explained to Nadine and to which she had consented; allowed, without her consent, an understudy to perform the actual procedure; engaged in unauthorized medical experimentation; and failed to disclose their research interest in performing the procedure. Plaintiff also sued Irvine Regional Hospital and Medical Center (Irvine Regional), alleging it failed to properly assess and document Nadine's condition after she arrived at their emergency facility manifesting symptoms of the surgical complication. Plaintiff contends the trial court erred when it sustained demurrers to several of plaintiff's causes of action without leave to amend, and granted defendants' motions for summary judgment as to plaintiff's

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[1] For convenience, we will sometimes refer to the Regents, Shivkumar, Cesario, and Swerdlow as the UCLA defendants.

remaining claims.

We conclude the trial court erred in granting summary judgment for Irvine Regional. In its motion, Irvine Regional sought to demonstrate plaintiff could not prove its nurses acted negligently, or that the nurses caused or contributed to Nadine's death. Plaintiff, however, raised a triable issue of fact on whether the nurses followed the standard of care in treating Nadine, and Irvine Regional failed to negate plaintiff's claim the nurses' negligence caused or contributed to Nadine's death.

We also conclude the trial court erred in granting summary judgment for the UCLA defendants. Although the trial court properly granted summary adjudication on plaintiff's wrongful death claim, the trial court erred in summarily adjudicating

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plaintiff's informed consent claim because the UCLA defendants' evidence failed to establish that no reasonable patient would have refused the ablation procedure had the doctors fully disclosed the risk of the particular complication that took Nadine's life. Accordingly, we reverse summary judgment in favor of Irvine Regional and the UCLA defendants, and affirm the orders granting summary adjudication in favor of the UCLA defendants on the first cause of action, and sustaining without leave to amend the demurrers of Shivkumar, Cesario, and UCLA to the fourth through 10th causes of action, and the demurrers of Swerdlow to the third through 10th causes of action.

I
FACTUAL AND PROCEDURAL BACKGROUND

The decedent, Nadine Secarea, suffered from cardiac arrhythmia, or irregular heartbeat. After three years of "annual hospitalizations" from the effects of arrhythmia, Nadine consulted cardiologist and electrophysiologist, Dr. Charles Swerdlow, to discuss the possibility of treating her condition with a cardiac catheter ablation. This procedure involves inserting a catheter, or wire, into a blood vessel and winding the catheter into the heart. Electrodes on the tip of the catheter measure the heart's electrical activity and determine the location of the "short circuit" that interrupts the heart's normal rhythms. Once doctors identify the area of the abnormal electrical activity, energy is applied to destroy a small amount of heart tissue. This results in the formation of lesions that halt the abnormal electrical disturbances from that area and restore the heart's natural rhythm.

Swerdlow and Shivkumar, who often worked as a team, arranged to perform Nadine's catheter ablation procedure at UCLA Medical Center. The evening before the procedure, Shivkumar met with Nadine and her husband to explain the procedure. Nadine reviewed and executed various informed consent forms during the meeting. On August 11, 2004, Swerdlow performed the ablation procedure, assisted by

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Cesario. At that time, Cesario was an electrophysiology fellow who had graduated from medical school eight years earlier, and had completed an internship and cardiology residency. The doctors completed the ablation procedure with no apparent complications, and Nadine went home the following day with instructions to follow up with Swerdlow in one month.

While at home on September 6, 2004, Nadine began experiencing visual disturbances along with tingling and numbness in her hands and arms. Plaintiff called 911, and an ambulance transported Nadine to Irvine Regional's emergency room. Doctors concluded she had suffered a transient ischemic attack, sometimes referred to as a mini-stroke, and transferred her to a telemetry unit for continuous electronic monitoring. On September 7, Nadine suffered a drop in blood pressure and a decrease in her level of consciousness. The following day, doctors determined Nadine had suffered a stroke affecting 80 to 90 percent of her cognitive abilities and probably would not regain consciousness. On September 12, Nadine's brain wave pattern showed she had suffered brain death, and plaintiff consented to her removal from life support. Nadine died shortly thereafter. An autopsy revealed Nadine had died from the effects of an atrio-esophageal fistula, a rare, but usually fatal, complication of the cardiac catheter ablation procedure.

Plaintiff sued defendants, alleging: (a) Nadine's doctors failed to advise her of the potential for the atrio-esophageal fistula complication; (b) Nadine consented to a limited empirical pulmonary vein isolation (LEPVI) procedure, which would have

minimized the number of burns, but the doctors performed an unauthorized wide area circumferential or "Pappone Technique" procedure instead; (c) Nadine conditioned her consent upon Swerdlow and Shivkumar performing the surgery as a team, but Shivkumar left the operating room shortly after Nadine was placed under anesthesia; (d) Nadine conditioned her consent on only Swerdlow and Shivkumar performing the operation, but Swerdlow allowed Cesario, an "understudy," to perform the procedure as part of his "on the job training"; (e) the doctors employed an esophageal stethoscope — a temperature

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probe designed to assist anesthesiologists — to protect against the atrio-esophageal fistula complication; use of the probe for this purpose was experimental, which(i) required FDA approval, (ii) violated the Regents' own policies and procedures, and (iii) was done without Nadine's consent; (f) Swerdlow, Shivkumar, and Cesario failed to disclose to Nadine their research interest in using the esophageal stethoscope to prevent the atrio-esophageal complication; and (g) following Nadine's arrival at the emergency room, Irvine Regional "failed to assemble the information and data needed to correctly diagnose and treat NADINE's critical condition." Plaintiff's second amended complaint set forth the following claims: First cause of action, wrongful death against all defendants; second cause of action, survival action for lack of informed consent against Swerdlow, Shivkumar, Cesario, and UCLA;third

cause of action, survival action for lack of informed consent — patient abandonment, against Swerdlow and Shivkumar; fourth cause of action, survival action for battery — ghost surgery against Swerdlow, Cesario, Shivkumar, and UCLA; fifth cause of action, survival action for battery — covert medical experimentations against Swerdlow, Shivkumar, Cesario, and UCLA; sixth cause of action, survival and individual action for fraud — "ghost surgery" against Swerdlow, Shivkumar, Cesario, and UCLA; seventh cause of action, survival and individual action for fraud — medical experimentation against Swerdlow, Shivkumar, and UCLA; eighth cause of action, survival action for negligence per se against Swerdlow, Shivkumar, Cesario, UCLA, and Vital Signs, Inc. (Vital Signs) [2]; ninth cause of action, product liability — negligence against Vital Signs, Swerdlow, Shivkumar, and UCLA; 10th cause of action, survival action for strict products liability — against Vital Signs, Swerdlow, Shivkumar, and UCLA; 11th cause of action, survival action based on Code of Civil Procedure section 377.20 against all defendants. 2 Plaintiff alleges Vital Signs manufactured the esophageal stethoscope usedto monitor temperatures in Nadine's esophagus during the ablation procedure.

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[2] Plaintiff alleges Vital Signs manufactured the esophageal stethoscope used to monitor temperatures in Nadine's esophagus during the ablation procedure.

The trial court sustained without leave to amend the demurrers of Shivkumar, Cesario, and UCLA to the fourth through 10th causes of action, and the demurrers of Swerdlow to the third through 10th causes of action. All of the defendants filed summary judgment motions, which the trial court granted. Plaintiff now appeals from the resulting judgment.

II
DISCUSSION

A. *The Trial Court Erred in Granting Summary Judgment for Irvine Regional*

Plaintiffs sued Irvine Regional for wrongful death (first cause of action) [3] and survival of claims under Code of Civil Procedure section 377.20 (11th cause of action). [4] The complaint alleges Irvine Regional "failed to assemble the information and data needed to correctly diagnose and treat NADINE's critical condition."

In support of its summary judgment motion, Irvine Regional submitted the declaration of registered

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[3] To prove a wrongful death claim, plaintiff must establish: "(1) a 'wrongful act or neglect' on the part of one or more persons that (2) 'cause[s]' (3) the 'death of [another] person' [citation] . . . ." (*Norgart v. Upjohn Co.* (1999) 21 Cal.4th 383, 390.)

[4] Code of Civil Procedure section 377.20, subdivision (a), provides, in relevant part: "Except as otherwise provided by statute, a cause of action for or against a person is not lost by reason of the person's death, but survives subject to the applicable limitations period."

nurse Ellen Daroszewski, an expert with a PhD in nursing. In her declaration, Daroszewski reviewed in detail the activities of the Irvine Regional nurses during Nadine's stay at the hospital, and opined their actions fell within the applicable standard of care. She also concluded the nursing services Irvine Regional rendered to Nadine did not cause or contribute to her death.

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In opposition, plaintiff submitted the declaration of Christine Farrell, a registered nurse and associate clinical professor at University of California, Los Angeles. Farrell provided a detailed explanation of situations where the actions of the Irvine Regional's nurses fell significantly below the standard of care for emergency room nurses, citing, for example, instances where the nurses failed to promptly perform a specific neurological assessment, failed to monitor heart rhythms, and failed to note the patient had vomited blood upon her arrival to the emergency room. Farrell concluded that the substandard care provided by Irvine Regional nurses and their lack of communication with the emergency room physicians contributed to Nadine's death.

The trial court observed that Farrell's declaration may have raised a triable issue of fact on whether the nurses met the applicable standard of care, but concluded the declaration failed to raise a triable issue of fact on causation. Specifically, the court noted Farrell "fails to identify how the 'substandard' nursing care, or how the lack of communication with the

emergency room physician more likely than not causes decedent's death. The fact that a breach in standard of care may have occurred does not automatically result in the cause of death in this case."

Plaintiff contends the trial court erred in granting summary judgment because Irvine Regional's motion did not address the hospital's vicarious liability for the emergency room physicians' alleged malpractice, and Irvine Regional failed to make a prima facie showing that the nurses' actions did not contribute to Nadine's death.

To support his first contention, plaintiff argues the hospital is liable for the acts of the emergency room physicians under theories of ostensible agency, breach of fiduciary duty, and elder and dependent adult abuse. The problem for the plaintiff on these theories is twofold. First, plaintiff fails to allege any of these theories in the second amended complaint. Second, plaintiff failed to raise the issue of Irvine Regional's vicarious liability for the actions of the emergency room doctors in the court below. Plaintiff opposed Irvine Regional's summary judgment motion solely by addressing the

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actions of the hospital's nurses, but did not claim Irvine Regional failed to negate vicarious liability for its physicians' alleged malpractice.

"The appellate court can deem an argument raised in an appeal from a grant of summary judgment waived if it was not raised below and requires

consideration of new factual questions." (*Zimmerman, Rosenfeld, Gersh & Leeds LLP v. Larson* (2005) 131 Cal.App.4th 1466, 1488.) The alleged malpractice of the emergency room physicians indisputably raises factual questions not addressed in plaintiff's separate statement or evidence. We therefore deem the argument waived.

We agree, however, with plaintiff's contention that Irvine Regional failed to meet its burden of production on causation. On a motion for summary judgment, the moving party "bears an initial burden of production to make a prima facie showing of the nonexistence of any triable issue of material fact; if he carries his burden of production, he causes a shift, and the opposing party is then subjected to a burden of production of his own to make a prima facie showing of the existence of a triable issue of material fact." (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850.) Once the moving party shows "'"that one or more elements of the cause of action, even if not separately pleaded, cannot be established," the burden shifts to the plaintiff to show the existence of a triable issue; to meet that burden, the plaintiff "may not rely upon the mere allegations or denials of its pleadings . . . but, instead, shall set forth the specific facts showing that a triable issue of material fact exists as to that cause of action . . . ." [Citations.]' [Citation.]" (*Village Nurseries v. Greenbaum* (2002) 101 Cal.App.4th 26, 35-36.)

To meet its burden of production, Irvine Regional relies on Daroszewski's declaration which cites all of the appropriate measures taken by the nurses, and concludes the nurses did not commit a negligent act or

omission that caused or contributed to Nadine's death. But Daroszewski fails to acknowledge or address any of the allegedly negligent acts and omissions cited in Farrell's declaration, and provides no opinion on whether such acts, if proven, could have contributed to Nadine's death. For example,

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Daroszewski does not explain how the nurses' alleged failure to perform a neurological assessment, monitor heart rhythms, or report that the patient had vomited blood upon her arrival to the emergency room could not have contributed to her death.

True, in performing her review of the medical records, Daroszewski might have considered the shortcomings Farrell identified, and determined none was serious enough to mention. But "an expert's opinion rendered without a reasoned explanation of why the underlying facts lead to the ultimate conclusion has no evidentiary value because an expert opinion is worth no more than the reasons and facts on which it is based." (*Bushling v. Fremont Medical Center* (2004) 117 Cal.App.4th 493, 510 (Bushling).) By failing to expressly acknowledge the factual bases for plaintiff's liability claim, the Daroszewski declaration lacks "a reasoned explanation of why the underlying facts lead to the ultimate conclusion" that the nurses' actions did not cause or contribute to Nadine's death.

We recognize Daroszewski's declaration could not directly address Farrell's declaration, given that Irvine Regional necessarily filed Daroszewski's

declaration first. But it was incumbent on Irvine Regional to learn the specific factual basis for plaintiffs' wrongful death claim, whether through demurrer or discovery, before moving for summary judgment. Had it done so, Irvine Regional could have met its burden of production on the issue of causation by having an appropriate medical expert specifically explain why, even if plaintiff proved his allegations concerning the nurses, their actions could not have caused or contributed to Nadine's death. Irvine Regional did not do so, and we therefore conclude the trial court erred in granting Irvine Regional's summary judgment.

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B. *The Trial Court Did Not Err in Granting Summary Adjudication on Plaintiff's First Cause of Action for Wrongful Death Against the UCLA Defendants*

In the second amended complaint, plaintiff's first cause of action alleges that "defendants, and each of them, so negligently, carelessly, recklessly, wantonly, and without consent, treated, experimented upon, misrepresented, provided such deficient care, monitoring, examination, diagnosis and other medical services so as to directly and proximately cause death to NADINE."

In support of their summary judgment motion, the UCLA defendants submitted the declaration of Andrea Natale, M.D., a medical professor at Ohio State University and a specialist in the treatment of abnormal heart rhythms. Natale is a nationally-recognized

electrophysiologist and cardiac expert who has personally performed over 2,000 ablations. The UCLA defendants also submitted the declaration of Douglas L. Packer, M.D., a medical professor at the Mayo School of Medicine, whose practice focuses on cardiac electrophysiology and research.

Plaintiff contends Natale's declaration is legally incompetent because it was executed outside of California, but did not reference "the laws of the State of California." (Code Civ. Proc., § 2015.5) [5] Plaintiff, however, never filed any objections

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to Natale's declaration, and therefore waived the point. (See, e.g., *Rader v. Thrasher* (1972) 22 Cal.App.3d 883,

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[5] Code of Civil Procedure section 2015.5 provides, in relevant part: "Whenever, under any law of this state or under any rule, regulation, order or requirement made pursuant to the law of this state, any matter is required or permitted to be supported, evidenced, established, or proved by the sworn statement, declaration, verification, certificate, oath, or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than a notary public), such matter may with like force and effect be supported, evidenced, established or proved by the unsworn statement, declaration,
verification, or certificate, in writing of such person which recites that it is certified or declared by him or her to be true under penalty of perjury, is subscribed by him or her, and (1), if executed within this state, states the date and place of execution, or (2), *if executed at any place, within or without this state, states the date of execution and that it is so certified or declared under the laws of the State of California*." (Italics added.)

886.) Natale concluded Nadine was an appropriate candidate for catheter ablation in August 2004, and the doctors' decision to perform the procedure met the applicable standard of care. She further opined: "The August 2004 catheter ablation was performed well within the standard of care. The medical records describe a text-book ablation. Every aspect of the procedure — including all of the power settings, temperature settings and burn times — was appropriate." Natale stated there was nothing in Nadine's medical history, or the way the procedure was performed, that made it more likely Nadine would develop the atrio-esophageal fistula that lead to her death. She explained there is no definitive way to prevent this complication, and concluded Nadine's death from the atrioesophageal fistula did not suggest the doctors departed from the standard of care.

Similarly, Packer testified the method employed during Nadine's ablation, "the wide area circumferential or Poppone [sic] technique, was well within the standard of care and is one that is used by the major centers treating patients with atrial fibrillation." He further opined that "[t]he power settings, temperature settings and burn times employed during the procedure by Dr. Swerdlow were appropriate and within the standard of care." He concluded with his "professional opinion that to a reasonable medical probability [Nadine's] demise was not attributable to any negligence on the part of Dr. Swerdlow."

Plaintiff did not submit an expert witness declaration from a physician, choosing to rely instead on his own declaration. Plaintiff compared the LEPVI

procedure he states was described to Nadine with the Pappone technique actually performed. He states these approaches were very different; "[t]he one Nadine consented to was a picture of simplicity while the one that was performed on her appeared to burn tissue needlessly." He also states that Cesario was "an inexperienced trainee electrophysiologist," and that the doctors "subjected Nadine to a medical research

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experiment . . . ." He concludes that the UCLA defendants "fatally injured [Nadine] and wrongly deprived [her] of her life."

Plaintiff's declaration fails to raise a triable issue of fact on whether the UCLA defendants' actions negligently or wrongfully caused Nadine's death. "[W]here a professional person is accused of negligence in failing to adhere to accepted standards within his profession[,] the accepted standards must be established only by qualified expert testimony . . . ." *(Osborn v. Irwin Memorial Blood Bank* (1992) 5 Cal.App.4th 234, 277.) Thus, "[w]here a medical process or procedure is not a matter of common knowledge, expert testimony is required to show that a doctor breached the standard of care of the medical community." *(Vandi v. Permanente Medical Group, Inc.* (1992) 7 Cal.App.4th 1064, 1071.) "'The "common knowledge" exception is principally limited to situations in which the plaintiff can invoke the doctrine of res ipsa loquitur, i.e., when a layperson "is able to say as a matter of common knowledge and observation that the consequences of professional

treatment were not such as ordinarily would have followed if due care had been exercised." [Citations.]' [Citation.]" (*Curtis v. Santa Clara Valley Medical Center* (2003) 110 Cal.App.4th 796, 801.) Thus, no expert opinion is required when a surgeon leaves scissors in a patient's abdomen after surgery or where "'the surgeon saws off the wrong leg.'" (Ibid.) But expert testimony is necessary to establish that a breach in the standard of care caused the injury. (See *Jones v. Ortho Pharmaceutical Corp.* (1985) 163 Cal.App.3d 396, 402.) Plaintiff is not a physician and is not qualified to opine on whether the UCLA defendants met the applicable standard of care in performing the cardiac ablation or whether their actions caused Nadine's death. These subjects are indisputably outside the common knowledge of lay people. Similarly, although the LEPVI technique may differ from the "the wide area circumferential" technique, the extent of the difference, if any, must be established by the testimony of a qualified physician. Both of the UCLA defendants' physician experts opined the doctors used an appropriate technique to ablate

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Nadine's heart and properly performed the procedure. "The fact that a particular injury suffered by a patient as the result of an operation is something that rarely occurs does not in itself prove that the injury was probably caused by the negligence of those in charge of the operation." (*Siverson v. Weber* (1962) 57 Cal.2d 834, 839; see also *Slater v. Kehoe* (1974) 38 Cal.App.3d 819,

830-831.)

"'When a defendant moves for summary judgment and supports his motion with expert declarations that his conduct fell within the community standard of care, he is entitled to summary judgment unless the plaintiff comes forward with conflicting expert evidence.'" (*Munro v. Regents of University of California* (1989) 215 Cal.App.3d 977,984-985.) Because plaintiff failed to counter the UCLA defendants' experts who declared the doctors met the applicable standard of care and their actions did not cause Nadine's demise, plaintiff failed to raise a triable issue of fact on these issues. The trial court therefore did not err in granting summary adjudication of plaintiff's wrongful death claim.

C. *The Trial Court Erred in Granting Summary Adjudication on Plaintiff's Second Cause of Action for Lack of Informed Consent.*

1. Whether the UCLA Defendants Should Have Warned Nadine of the Risk of Death from the Atrio-Esophageal Fistula Complication Presents a Triable Issue of Fact

a. Adequacy of the Disclosures Given

There is no dispute the UCLA defendants failed to warn Nadine of the risk of death from the atrio-esophageal fistula complication that took her life. Rather, the issue raised is whether they were required to warn Nadine about this specific

complication. "'"[A]s an integral part of the physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed

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therapy and of the dangers inherently and potentially involved in each." [Citation.] The scope of a physician's duty to disclose is measured by the amount of knowledge a patient needs in order to make an informed choice. All information material to the patient's decision should be given. [Citation.] [¶] Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure. [Citations.] To be material, a fact must also be one which is not commonly appreciated. [Citation.] If the physician knows or should know of a patient's unique concerns or lack of familiarity with medical procedures, this may expand the scope of required disclosure. [Citation.]' [Citation.] The physician's duty to disclose is twofold. "First, a physician must disclose to the patient the potential of death, serious harm, and other complications associated with a proposed procedure. [Citation.]' [Citation.] 'Second, "[b]eyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as a skilled practitioner of good standing would provide under similar circumstances." [Citation.]' [Citation.]" (*Wilson v. Merritt* (2006) 142 Cal.App.4th 1125, 1133-1134.)

"[T]he patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required; the patient is concerned with the risk of death or bodily harm, and problems of recuperation. . . . [¶] However, . . . when a given procedure inherently involves a known risk of death or serious bodily harm, a medical doctor has a duty to disclose to his patient the potential of death or serious harm, and to explain in lay terms the complications that might possibly occur." (*Cobbs v. Grant* (1972) 8 Cal.3d 229, 244 (Cobbs).)

"The scope of a physician's duty to disclose is set by law rather than by the custom of physicians." (*Truman v. Thomas* (1980) 27 Cal.3d 285, 292, fn. 3 (Truman).) Accordingly, the question whether a doctor has a legal duty to disclose in a particular

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situation is primarily a question for the jury, not an expert, to determine. (*Wilson v. Merritt* (2006) 142 Cal.App.4th 1125, 1134 (Wilson).) The Supreme Court has "stressed the paramount role of the trier of fact in informed consent cases," recognizing, "for example, that questions such as whether the danger posed by a failure to disclose a particular risk is remote, whether the risk was or was not commonly known, and whether circumstances unique to a given case supported a duty of disclosure were matters for the jury to decide." (*Arato v. Avedon* (1993) 5 Cal.4th 1172, 1184.) "[T]he touchstone of the physician's duty of disclosure is the patient's need for 'adequate information to enable an

intelligent choice,' a peculiarly fact-bound assessment which juries are especially well suited to make." (Id. at p. 1186.)

Expert testimony, however, does have its place in informed consent cases. For example, an expert should testify on the standard of practice in situations where, beyond the minimal disclosure of the potential of death, serious harm, and other complications, the doctor must disclose "'"such additional information as a skilled practitioner of good standing would provide under similar circumstances." [Citation.]' [Citation.]" *(Wilson, supra*, 142 Cal.App.4th at p. 1134.)

To meet their burden of production on the informed consent issue, the UCLA defendants cited the forms Nadine executed the day before the procedure. Specifically, Nadine executed the following forms: "Cardiac Catheter Ablation," which disclosed the risk of cardiac perforation and included the warning, "You may die from the procedure"; "Cardiac Catheterization," which disclosed, "You may die from the procedure," and stated the probability of death as "1 in 1000"; "Transesophageal Echocardiogram," which disclosed the possibility of injury to the esophagus and adjacent tissue; and "Electrophysiology (EP) Study," which disclosed risks of cardiac perforation and heart attack. The UCLA defendants also relied on Natale's declaration that the atrioesophageal fistula complication is rare, stating: "Although some in the electrophysiology

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community believe that the incidence of [atrio-esophageal fistula] is as high as 1 percent, only about 18 atrio-esophageal fistulas have been reported worldwide out of approximately 20,000 to 30,000 catheter ablations for atrial fibrilliation — suggesting that the risk of this complication is far less than 1 percent." Natale opined: "The standard of care required that [Nadine] be informed of the risk of death, and the medical records indicate that she was informed of and accepted this risk. That she accepted the risk of death indicates that she accepted the risk of an atrio-esophageal fistula-related death. The standard of care did not require that [Nadine] be informed of each and every way she could die. Knowing that death could occur, rather than knowing how it could occur, is the important factor for a reasonable patient to decide whether to undergo or decline a catheter ablation. The standard of care did not require the specific disclosure of the risk of atrio-esophageal fistula or death from an atrio-esophageal fistula."

In opposition, the plaintiff relies on his declaration describing the consultation he and Nadine had with Shivkumar the evening before the procedure. Plaintiff pointed out to Shivkumar that warning number 12 on the cardiac catheter ablation consent form, identifying the risk of death as a complication, was ambiguous and vague. Plaintiff states: "I asked Dr. Shivkumar if he might qualify this warning by telling Nadine and me what kinds of conditions might result in the death of a patient undergoing a catheter ablation. He replied with a list of infirmities which he believed could compromise a patient's chances of having a safe,

if not successful ablation. I asked him if Nadine was at risk for any of these problems. He answered 'no.'"

We conclude Natale's opinion fails to establish as a matter of law that Nadine's doctors had no obligation to disclose the risk of the atrio-esophageal fistula complication. True, Natale noted that only 18 cases of the complication have been reported out of 20,000 to 30,000 procedures, suggesting a complication rate of less than one-tenth of one percent. But Natale also noted that "some in the electrophysiology community believe that the incidence of [atrio-esophageal fistula] is as high as

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1 percent . . . ." The only consent form referencing a specific probability of death was the Cardiac Catheter form, which described the probability of death as "1 in 1000." Given at least some professionals in the electrophysiology community believe the atrio-esophageal fistula complication is as high as 1 in 100 — 10 times higher than the risk disclosed — and the specific information plaintiff requested from Shivkumar, a jury could determine Shivkumar provided inadequate disclosures. Moreover, plaintiff's specific questions regarding conditions potentially resulting in death demonstrated unique concerns expanding the scope of the required disclosure. (See *Truman, supra*, 27 Cal.3d at p. 291.) In sum, the evidence presented raised a triable issue of fact on whether the doctors should have informed Nadine of the specific risk that led to her death.

The UCLA defendants rely on *Morgenroth v. Pacific Medical Center, Inc.* (1976) 54 Cal.App.3d 521, 534, for the proposition that disclosure requirements are met when the doctor informs a patient of the risk of death. There, a patient sued his doctor after suffering a disabling stroke during a coronary anteriogram. The patient conceded the doctor had warned him of the risk of death or serious disease, but argued the doctor should have provided a specific warning as to stroke. (Id. at p. 530.) Affirming the trial court's nonsuit for the doctor, the court concluded, "the information that a procedure carries the risk of death or serious disease in lay language sufficiently explains the range of complications that might occur, including a stroke." (Id. at p. 534.) The court also determined that the question of what "'additional information as a skilled practitioner of good standing would provide under similar circumstances,'" was solely a matter for expert testimony, which the patient failed to present. (Ibid.)

Morgenroth is distinguishable. Here, plaintiff and Nadine, upon reading the informed consent form disclosing the risk of death, requested more detailed information on how death may occur and whether these complications posed a risk of death for Nadine. Nothing in Morgenroth suggests the plaintiff had requested any further clarification.

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b. Causation

A physician is liable for failing to provide adequate disclosure of known risks only where there is a "causal relationship between the physician's failure to inform and the injury to the plaintiff. Such causal connection arises only if it is established that had revelation been made consent to treatment would not have been given." (*Cobbs, supra*, 8 Cal.3d at p. 245.) "[C]ausation must be established by an objective test: that is, the plaintiff must show that reasonable 'prudent person[s]' in the patient's position would decline the procedure if they knew all significant perils." (*Spann v. Irwin Memorial Blood Centers* (1995) 34 Cal.App.4th 644, 657.)

In her declaration, Natale addressed the question of whether the doctors' failure to inform Nadine of the specific atrio-esophageal risk would have affected her decision to have the procedure. Based on her review of Nadine's medical records, Natale determined that Nadine suffered from chronic and symptomatic atrial fibrillation, a condition "associated with heart failure, blood clots, a five to sevenfold increase in stroke, and increased mortality from heart disease." Natale determined that Nadine's atrial fibrillation was resistant to antiarrhythmic medications, and had become progressively more frequent and intense. She concluded Nadine was an appropriate candidate for the catheter ablation procedure in August 2004, and nothing about Nadine's condition or medical history increased the risk of atrio-esophageal fistula or death.

On the specific issue of causation, Natale stated: "To a reasonable medical probability,

there is no causal relationship between the alleged failure to inform of the risk of atrio-esophageal fistula and the death of [Nadine]. It cannot be stated to a reasonable medical probability that a reasonable patient with chronic and symptomatic atrial fibrillation would have declined the catheter ablation if the specific risk of atrioesophageal fistula [had] been disclosed. In my professional opinion, a reasonable patient with [Nadine]'s condition could not have declined the catheter ablation even if this specific risk had been disclosed. This is because the risks of heart failure, stroke and

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death increased significantly without a catheter ablation. Given the gravity of these risks, any reasonable person would have made the same decision as [Nadine] made — i.e., to undergo the ablation."

Natale's opinion regarding what a reasonable patient in Nadine's position would do is beyond her expertise and must be disregarded. "A medical doctor, being the expert, appreciates the risks inherent in the procedure he is prescribing, the risks of a decision not to undergo the treatment, and the probability of a successful outcome of the treatment. But once this information has been disclosed, that aspect of the doctor's expert function has been performed. The weighing of these risks against the individual subjective fears and hopes of the patient is not an expert skill." (*Cobbs, supra*, 8 Cal.3d at p. 243.)

That an expert is incompetent to testify

regarding whether a reasonable patient would consent to a procedure, does not mean a court may never grant summary judgment on an informed consent claim. For example, where the risks of harm from a procedure are minimal, and the risks of foregoing the procedure pose a high risk of harm or death, a medical expert's testimony on those risks may establish as a matter of law that no reasonable patient would refuse consent. But this is not the present situation. True, Natale established that Nadine suffered from chronic and symptomatic atrial fibrillation that had become progressively more frequent and intense, and was resistant to medication. Natale also opined that Nadine presented no special risks of complication from the procedure, and declining treatment would leave her at an increased risk for stroke and heart attack. But Natale did not specify to what degree, if any, the increased risks for stroke or heart attack exceeded the risks from the procedure. Having provided insufficient information to allow us to determine, as a matter of law, that no reasonable patient would have refused the ablation procedure, the UCLA defendants failed to meet their burden. We therefore conclude the trial court erred in granting summary judgment for the UCLA defendants.

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D. *The Trial Court Did Not Err in Sustaining Demurrers Without Leave to Amend to Plaintiff's Third Through Eighth Causes of Action*

1. Third Cause of Action

In his third cause of action for "Lack of Consent — Patient Abandonment," plaintiff alleges Nadine conditioned her surgical consent on Swerdlow and Shivkumar acting as a team during her procedure. The trial court sustained Swerdlow's demurrer to this cause of action without leave to amend because the facts did not demonstrate Swerdlow had a legal obligation to prevent Shivkumar from leaving the operating room. The court further held that the allegations did not establish Shivkumar's abandonment of Nadine. Plaintiff does not allege the doctors explained to Nadine how they would work as a team, and Shivkumar's alleged departure shortly after Nadine was placed under anesthesia does not demonstrate the two doctors did not actually work together. We agree with the trial court. Absent allegations the doctors agreed to perform specific aspects of the procedure, Shivkumar's early departure does not by itself demonstrate patient abandonment.

2. Fourth Cause of Action

Plaintiff's fourth cause of action, "Battery — Ghost Surgery," alleges the UCLA defendants committed a battery on Nadine by having Cesario perform the ablation procedure.

"As a general rule, one who consents to a touching cannot recover in an action for battery. [Citation.] Thus, one who gives informed consent to a surgery cannot recover for resulting harm under a theory of battery. [Citations.] However, it is well recognized a person may place conditions on the

consent. If the actor exceeds the terms or conditions of the consent, the consent does not protect the actor from liability for the excessive act. [Citation.] [¶] The rule of conditional consent has been applied in battery actions against physicians and surgeons in California . . . . [Citations.]" (*Ashcraft v.*

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King (1991) 228 Cal.App.3d 604, 609-610.) "'There are three elements to a claim for medical battery under a violation of conditional consent: the patient must show his consent was conditional; the doctor intentionally violated the condition while providing treatment; and the patient suffered harm as a result of the doctor's violation of the condition. [Citation.]' [Citation.]" (*Piedra v. Dugan* (2004) 123 Cal.App.4th 1483, 1497-1498.)

Our ruling upholding summary adjudication on plaintiff's wrongful death cause of action conclusively negates the third element of his battery claim. Specifically, when a grant of summary judgment or summary adjudication demonstrates the plaintiff cannot establish an element of a related cause of action, any error by the trial court in sustaining a demurrer to the related cause of action is deemed harmless. (*Thompson v. Halvonik* (1995) 36 Cal.App.4th 657, 664.) In connection with their summary judgment motion, the UCLA defendants established the doctors performed the ablation procedure on Nadine in a competent and appropriate manner, and plaintiff was unable to establish a triable issue regarding this fact. Because

plaintiff did not demonstrate harm arising from Cesario's participation in the operation, we do not disturb the trial court's sustaining of demurrers to plaintiff's battery cause of action without leave to amend.

3. Fifth, Seventh, and Eighth Causes of Action

Plaintiffs' fifth cause of action for battery based on covert medical experimentation alleges defendants "performed an experimental form of the ablation procedure upon NADINE, using her need for medical treatment as an opportunity to surreptitiously engage in a dangerous and purely speculative course of conduct . . . ." Similarly, plaintiff's seventh cause of action for fraud based on medical experimentation also alleged defendants "engage[d] in an unlawful, dangerous and purely speculative course of conduct . . . ." Finally, plaintiff's eighth cause of action for negligence per se

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alleges the UCLA defendants violated unspecified statutes and regulations by performing "unlawful medical experimentation" on Nadine. In support of summary adjudication on plaintiff's wrongful death cause of action, the UCLA defendants established the specific procedure performed on Nadine, including the use of and esophageal temperature probe, was not "experimental or investigational" at the time of the operation. Plaintiff provided no competent evidence rebutting this point to the trial court. Nonetheless,

plaintiff requests we judicially notice a host of documents relating to medical experimentation. The documents were neither presented to the trial court nor addressed in the parties' briefs. Plaintiff acknowledges the "'eleventh hour'" nature of his judicial notice request, but argues that logistical problems and personal health issues prevented him from presenting the material sooner.

"Reviewing courts generally do not take judicial notice of evidence not presented to the trial court. Rather, . . . 'when reviewing the correctness of a trial court's judgment, an appellate court will consider only matters which were part of the record at the time the judgment was entered.' [Citation.]" (*Vons Companies, Inc. v. Seabest Foods, Inc.* (1996) 14 Cal.4th 434, 444, fn. 3.) We conclude plaintiff's explanation for his failure to present the proffered evidence sooner does not justify departure from the general rule that an appellate court will consider only the evidence presented to the trial court. Accordingly, we deny plaintiff's request for judicial notice. We conclude our ruling on plaintiff's wrongful death claim renders harmless any error in the trial court's demurrer ruling on the fifth, seventh, and eighth causes of action.

4. Sixth Cause of Action

Plaintiff's sixth cause of action for fraud, entitled "ghost surgery," alleges Swerdlow and Shivkumar falsely promised Nadine they would perform the surgery as a team to induce Nadine to undergo the surgery and thereby use her body as "'on-the-job

training' for understudy Dr. Cesario . . . ." Plaintiff alleges Nadine was deprived of the

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skill and experience of Swerdlow and Shivkumar and suffered the atrio-esophageal complication as a result. Again, plaintiff was unable to raise a triable issue of fact in response to the UCLA defendants' evidence that Cesario performed the ablation procedure within the standard of care. Because plaintiff is unable to demonstrate causation and damages, any error in sustaining demurrers to the sixth cause of action is harmless.

III
DISPOSITION

Summary judgment in favor of Irvine Regional and the UCLA defendants is reversed. The orders granting summary adjudication in favor of the UCLA defendants on the first cause of action and sustaining without leave to amend the demurrers of Shivkumar, Cesario, and UCLA to the fourth through 10th causes of action, and the demurrers of Swerdlow to the third through 10th causes of action are affirmed. In the interests of justice, each party is to bear its own costs of this appeal.

ARONSON, J.

WE CONCUR:
BEDSWORTH, ACTING P. J.
IKOLA, J.

California Court of Appeals Modified Opinion

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[Modified Appellate Opinion: Page 1]

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FOURTH APPELLATE DISTRICT
DIVISION THREE

VALER V. SECAREA, JR.,
Plaintiff and Appellant,
v.
REGENTS OF THE UNIVERSITY OF CALIFORNIA et al.,
Defendants and Respondents.

G037651
(Super. Ct. No. 05CC10019)

ORDER MODIFYING OPINION AND DENYING PETITION FOR REHEARING; NO CHANGE IN JUDGMENT

It is ordered that the opinion filed herein on November 20, 2008, be modified as follows:

On page 8, at the conclusion of the first full paragraph, after the sentence ending with "deem the argument waived," add as footnote 5 the following footnote, which will require renumbering of the subsequent footnote:

> Of course, plaintiff's failure to raise the issue in opposition to Irvine Regional's summary judgment motion does not foreclose plaintiff from raising the issue in future proceedings, including trial.

[Modified Appellate Opinion: Page 2]

On page 10, delete the second sentence of the third paragraph which begins "Plaintiff, however, never filed any objections to Natale's declaration" and replace it with the following sentences:

> Plaintiff, however, never raised this objection either in writing or orally at the summary judgment hearing. Plaintiff asserts the trial court refused to allow any evidentiary objections during oral argument, thus preventing the issue from being raised. Not so. A review of the hearing transcript reveals the trial court gave plaintiffs counsel substantial time to argue all of the points he desired before

ruling. Indeed, after extensive argument and discussion, the court told counsel "I'll give you the last bite of the apple . . . ." Later, the court invited counsel: "[I]f you want to make a record, I'll be more than happy to let you do so." Yet counsel remained silent regarding any defects in the Natale declaration. After the trial court had ruled on the summary judgment motion, defendants' noted that plaintiff may appeal the ruling and asked the court to rule on their previously filed evidentiary objections. After complying with defendant's request, plaintiffs counsel stated: "Your honor, would it be, at this point, that we can argue the evidentiary objections?" The court responded: "I don't argue evidentiary objections. I just go ahead and read the paperwork, look at the objections and rule on them, so — because otherwise, we have speaking objections, and I don't do that." Significantly, plaintiffs counsel requested the opportunity to argue objections, and never informed the court he wished to make new objections. Because plaintiff failed to raise the defect in the Natale declaration in the trial court, we conclude plaintiff failed to preserve this issue for appeal.

[Modified Appellate Opinion: Page 3]

This modification does not change the judgment. The petition for rehearing is DENIED.

ARONSON, J.

WE CONCUR:
BEDSWORTH, ACTING, P. J.
IKOLA, J.

Court of Appeal, Fourth Appellate District,
Div. 3 - No. G037651
S169447

IN THE SUPREME COURT OF CALIFORNIA

En Banc

VALER V. SECAREA, JR., Petitioner and Appellant,

v.

REGENTS OF THE UNIVERSITY OF CALIFORNIA, et al., Defendants and Respondents

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The petition for review is denied.

George, C.J., was absent and did not participate.

SUPREME COURT
FILED
FEB 18 2009
Frederick K. Ohlrich Clerk

Deputy

CORRIGAN
Acting Chief justice

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Constitutional and Statutory Provisions

Constitutional Provisions

A. U.S. Const. amend. XIV § 1

The first section of the Fourteenth Amendment to the United States Constitution provides in pertinent part as follows:

No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

B. U.S. Const. amend. V

The Fifth Amendment to the United States Constitution provides in pertinent part:

No person shall be ... deprived of life, liberty, or property, without due process of law.

C. U.S. Const. amend. IX

The Ninth Amendment to the United States Constitution provides in pertinent part:

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people

D. U.S. Const., article VI, par. 2: Supremacy Clause

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the contrary notwithstanding.

Statutory Provisions

A. 21 USC 321(h) Device

The term "device" (except when used in paragraph (n) of this section and in sections 331 (i), 343 (f), 352 (c), and 362 (c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

B. 21 USC 360j(g) Exemption for Devices for Investigational Use

Statutory provisions transcribed in relevant part:

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2) (A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device

subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption–

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing–

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if–

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing

has been approved by such committee), for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing tha

there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

Code of Federal Regulations

A. 21CFR 801.4 Meaning of Intended Uses

The wordsintended uses or words of similar import in 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him

notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

B. 21 CFR 812 IDE Requirements

1. 21 CFR 812.1 Scope

(A) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under 812.30 or considered approved under 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder: Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section

516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) except for the requirements found in 820.30, if applicable (unless the sponsor states an intention to comply with these requirements under 812.20(b)(3) or 812.140(b)(4)(v)) and color additive requirements under section 721.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

2. 21 CFR 812.2 Applicability

(a) General. This part applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in paragraph (c) of this section.

(b) Abbreviated requirements. The following categories of investigations are considered to have approved applications for IDE's, unless FDA has notified a sponsor under 812.20(a) that approval of an application is required:

> (1) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:
>
> > (i) Labels the device in accordance with 812.5;

(ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under part 50 and documents it, unless documentation is waived by an IRB under 56.109(c).

(iv) Complies with the requirements of 812.46 with respect to monitoring investigations;

(v) Maintains the records required under 812.140(b) (4) and (5) and makes the reports required under 812.150(b) (1) through (3) and (5) through (10);

(vi) Ensures that participating investigators maintain the records required by 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and

(vii) Complies with the prohibitions in 812.7 against promotion and other practices.

(2) An investigation of a device other than one subject to paragraph (e) of this section, if the investigation was begun on or before July 16,

1980, and to be completed, and is completed, on or before January 19, 1981.

(c) Exempted investigations. This part, with the exception of 812.119, does not apply to investigations of the following categories of devices:

(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

(3) A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:

(i) Is noninvasive,

(ii) Does not require an invasive sampling procedure that presents significant risk,

(iii) Does not by design or intention introduce energy into a subject, and

(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

(5) A device intended solely for veterinary use.

(6) A device shipped solely for research on or with laboratory animals and labeled in accordance with 812.5(c).

(7) A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

(d) Limit on certain exemptions. In the case of class II or class III device described in paragraph (c)(1) or (2) of this section, this part applies beginning on the date stipulated in an FDA regulation or order that calls for the submission of premarket approval applications for an unapproved class III device, or establishes a performance standard for a class II device.

(e) Investigations subject to IND's. A sponsor that, on July 16, 1980, has an effective investigational new drug application (IND) for an investigation of a device shall continue to comply with the requirements of part 312 until 90 days after that date. To continue the investigation after that date, a sponsor shall comply with paragraph (b)(1) of this section, if the device is not a significant risk device, or shall have obtained FDA approval under 812.30 of an IDE application for the investigation of the device.

3. 21 CFR 812.3 Definitions

(a) Act means the Federal Food, Drug, and Cosmetic Act (sections 201-901, 52 Stat. 1040et seq ., as amended (21 U.S.C. 301-392)).

(b) Custom device means a device that:

(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

(2) Is not generally available to, or generally used by, other physicians or dentists;

(3) Is not generally available in finished form for purchase or for dispensing upon prescription;

(4) Is not offered for commercial distribution

through labeling or advertising; and

(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

(c) FDA means the Food and Drug Administration.

(d) Implant means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" for purposes of this part.

(e) Institution means a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as "facility" in section 520(g) of the act.

(f) Institutional review board (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in

conformance with part 56. The term has the same meaning as "institutional review committee" in section 520(g) of the act.

(g) Investigational device means a device, including a transitional device, that is the object of an investigation.

(h) Investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

(i) Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(j) Monitor, when used as a noun, means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization.Monitor, when used as a verb, means to oversee an investigation.

(k) Noninvasive, when applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth

beyond the pharynx,[6] the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

(l) Person includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

(m) Significant risk device means an investigational device that:

(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

(2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

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[6] The pharynx is that part of the digestive tube which is placed behind the nasal cavities, mouth, and larynx. It is a musculomembranous tube, somewhat conical in form, with the base upward, and the apex downward, extending from the under surface of the skull to the level of the cricoid cartilage in front, and that of the sixth cervical vertebra behind. (http://education.yahoo.com/reference/gray/subjects/subject/244)

(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

(n) Sponsor means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

(o) Sponsor-investigator means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

(p) Subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may

have a medical condition or disease.

(q) Termination means a discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of an investigation before completion.

(r) Transitional device means a device subject to section 520(l) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

(s) Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

4. 21 CFR 812.20 IDE Application

(a) Submission.

(1) A sponsor shall submit an application to FDA if the sponsor intends to use a significant risk device in an investigation, intends to conduct an investigation that involves an exception from informed consent under 50.24 of this chapter, or if FDA notifies the sponsor that an application is required for an investigation.

(2) A sponsor shall not begin an investigation for which FDA's approval of an application is required until FDA has approved the application.

C. 21 CFR 50 Informed Consent

1. 21 CFR. 50.20 General Requirements

Except as provided in 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2. 21 CFR 50.25 Elements of Informed Consent

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be

provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b)Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to

withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(d) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

D. 21 CFR 56 Institutional Review Boards

21 CFR 56 is quite lengthy, thus only the sections relevant to this litigation have been reproduced.

1. 21 CFR 56.103 Circumstances in which IRB review is required.

(a) Except as provided in 56.104 and 56.105, any clinical investigation which must meet the requirements for

prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

[46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

Sec. 56.109 IRB review of research.

(a) An IRB shall review and have authority to approve,

require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with 50.27 of this chapter, except as follows:

(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or

(2) The IRB may, for some or all subjects, find that the requirements in 50.24 of this chapter for an exception from informed consent for emergency research are met.

(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.

(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(g) An IRB shall provide in writing to the sponsor of research involving an exception to informed consent under 50.24 of this chapter a copy of information that has been publicly disclosed under 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the

information disclosed to FDA.

(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter, at the time of its initial review of the research. When some or all of the subjects in a study that is ongoing on April 30, 2001 are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date.

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Excerpts from the AOB:
Regulations as a Standard of Care

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Appellant's Opening Brief

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m. Regulations as a Standard of Care

Medical experimentation of the kind Nadine was subjected to is governed by rules and regulations of federal and State governments and by the University of California, *as a standard of care*. (1.CT.77-105 [SAC §§15-108]; 1.CT.124-125 [SAC §§200-201]) A federal statute or regulation may be adopted as a standard of care. (*DiRosa v. Showa Denko K.K.* (1996) 44 Cal.App.4th 799, 808; also *Evraets v. Intermedics Intraocular, Inc.* (1994) 29 Cal.App.4th 779, 791-792 and *Sierra-Bay Federal Land Bank Assn. v. Superior Court* (1991) 227 Cal.App.3d 318, 332.)

At the core of these regulations is an expanded disclosure requirement and patient/subject's informed consent.

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The University of California Contract and Grant Manual, Chapter 18, Protection of Research Subjects (hereinafter, *UC Grant Manual*), states, at section 18-220, Applicability of Governmental Regulations and Policies to All Research, that: "regulations of the Department of Health and Human Services (HHS), set forth in 45 CFR Part 46, are applicable to all research involving human subjects . . ." (1.CT.98:13-20) Within this framework, a researcher has a duty to inform the

subject of *all risks that are reasonably foreseeable*, consistent with disclosures required by 45 CFR 46.116. (Section 18-220 of the *UC Grant Manual*; *Grimes v. Kennedy Krieger Institute, Inc.* (2001) 366 Md. 29 [782 A.2d 807]).

In concert with the *UC Contract and Grant Manual*, the UCLA Investigator's Manual for the Protection of Human Subjects (*UCLA Investigator's Manual*), requires both *prior* IRB (Institutional Review Board) approval and Nadine's informed consent for the medical experiment she (and other patients) were subjected to. (1.CT.104:8-9; 1.CT.209; UCLA Investigator's Manual, page 7-1; 1.CT.111-112)

Moreover, respondent Regents have declared, under the UCLA Assurance Policies (1.CT.1058-1069), in Part 2(I)(A), that:

> This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state, or local laws as they may relate to such research.

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Respondent Regents have determined that adherence to Health & Safety Code § 24170, et. seq. (Protection of Human Subjects in Medical Experimentation Act or PHSMEA) is a mandatory obligation for all University of California investigators. (1.CT.95-96 [SAC §§89-90]; 1.CT.167-169).

Lastly, the California Constitution establishes the Regents as a "public trust ... with full powers of organization and government." (Caifornia Constitution, art. IX, § 9(a)), thus, Regents' regulations regarding human experimentation have the force of law. (*Regents of University of California v. City of Santa Monica* (1978) 77 Cal.App.3d 130, 135, citing *Hamilton v. Regents* (1934) 293 U.S. 245; *Apte v. Regents of University of California* (1988) 198 Cal.App.3d 1084, 1090.)

Consequently, respondent Regents must adhere to their own regulations.

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Due Process Deprivation at MSJ Hearing (Appellant's Opening Brief)

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C. The Trial Court Erred in Granting Summary Judgments

1. Due Process Right Deprivation

During the hearing on the Summary Judgment motions, Appellant's attorney asked to address evidentiary issues. The lower court responded:

> "I don't argue evidentiary objections. . . I just go ahead and read the paperwork, look at the objections and rule on them, so – because otherwise, we have speaking objections, and I don't do that." (RT 36:24-37:3)

But, the trial court is required to hear oral argument. (*Mediterranean Const. Co. v. State Farm Fire & Cas. Co.* (1998) 66 Cal.App.4th 257, 262; CCP §437c(b); California Rules of Court, Rule 3.1352 (former Rule 343)) Due process minimally contemplates being fully and fairly heard before an impartial decisionmaker. (*Catchpole v. Brannon*

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(1995) 36 Cal.App.4th 237, 245.) "He who decides must hear." (*Morgan v. United States* (1936) 29 U.S. 468

[80 L.Ed. 1288; 56 S.Ct. 906].) A judgment rendered without due process is a nullity. *(Laing v. Rigney* (1896) 16 S.Ct. 366 [160 U.S. 531])

2. Refusal to hear evidentiary argument was prejudicial

Silencing Appellant on evidentiary issues, was tantamount to silencing his opposition to the motions themselves, because a Motion for Summary Judgment stands or falls on the basis of evidence -- admitted and excluded (CCP § 437c). Appellant was deprived of an opportunity to take issue with Respondents' evidence, *at the only time in which it could make a difference to the outcome of the proceeding*. As a consequence, the trial court prejudicially deprived this Appellant-Plaintiff a hearing on the merits.

a. Refusal to hear Appellant's objections to Respondents' evidence allowed an incompetent declaration to be admitted

The declaration by Dr. Andrea Natale in support of the Motion for Summary Judgment of Regents, and Drs. Shivkumar and Cesario is legally incomoetent. Declarations signed under penalty of perjury outside this state do not satisfy Code of Civil Procedure § 2015.5, and are not admissible in summary judgment and other authorized proceedings, unless they are certified as true "under the laws of the State of California." (*Kulshrestha v. First Union Commercial Corp*. (2004)33 Cal.4th 601, 618).

Dr. Natale's declaration does not appear to satisfy this requirement. (2.CT. 566:23-24; 3.CT.781:23-24).

b. The trial court erred in sustaining objections to Valer's declaration where the statements related to events he witnessed, his state of mind at those times, admissions made by the respondents and descriptions of respondents behavior as party admissions

Events personally witnessed (entire Declaration) is primary evidence. (*People v. Johnson* (1974) 39 Cal.App.3d 749, 763)

Valer describes what he and Nadine knew, when they knew it, and how their collaborative state of mind, plans and decisions were influenced by what they were told and not told by respondents. (¶¶ 1-9, 11-16, 19-21, 23-41) (Evidence Code § 1250; *Smith v Slifer* (1969) 1 Cal.App.3d 748 [81 Cal.Rptr 87])

His recounting of respondents statements including e-mails written by them, were admissible as party admissions. (¶¶ 7-8, 11, 23- 24, 27-28, 33, 36-37, 40, 46-47, 49, 51-55, 57-58, 61-62) (Evidence Code § 1220-1227; *People v Alvarez* (1968) 268 Cal App 2d 297, [73 Cal Rptr 753])

(¶2) Observations of Nadine's physical suffering required no medical expertise. (*Sweeney v Workers' Comp. Appeals Bd.* (1968) 264 Cal App 2d 296 [70 Cal

Rptr 462])

Lastly, Valer's assessment, as an Aerospace Engineer, of the unwarranted application of the Vital Temp probe, is an engineering question,

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not a medical one. (Evidence Code § 720(a) and (b); *Jeffer, Mangels & Butler v. Glickman* (1991) 234 Cal.App.3d 1432)

Consequently, objections to Valer's Declartion (3.CT.794-806) should have been overruled.

c. The objections to the e-mails exchanged by Valer and Nadine and Drs. Swerdlow and Shivkumar should have been overruled becauset they contained party admissions and were authenticated by content and circumstances

An e-mail is a writing, (Evidence Code § 250) There is no limit to the ways a writing can be authenticated. (Evidence Code § 1410) Circumstantial evidence, content and location are all valid means of authentication. (*People v. Gibson* (2001) 90 Cal.App.4th 371, 383)

Th ee-mails are authenticated by Valer's descriptions and references which are likely to be known only to a participant in these events as Valer had declared that he was as a percipient witness, (3.CT.794) (Evidence Code §§ 1400, 1401, 1413); and by their

contents, (Evidence Code § 1421; *People v. Babbitt* (1988) 45 Cal.3d 660, 685; *McAllister v. George* (1977) 73 Cal.App.3d 258, 263); by respondents' reply, admissions made by them, and their conduct in acting upon them. (Evidence Code §§ 1414(a) and (b), and 1420.)

In addition, Evidence Code § 1413 permits authentication "by anyone who saw the writing made or executed, including a subscribing witness." Valer provided the required foundation: "I am a personal witness

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to all that I describe." (3-CT-794:3) And, Valer and Nadine share a common e-mail account, "vsecarea@arts-n-engineering.com." Moreover, that Respondents' used of some of the very e-mail text to which they also object, is an admission of authenticity. (Evidence Code §1414; Evidence Code § 1221) These e-mails are not considered hearsay and are admissible show Nadine's state of mind, such as how important the selection of the right physicians or "team" was to her, (Evidence Code § 1250 et seq.; *Rufo v. Simpson* (2001) 86 Cal.App.4th 573, 591-595); or to prove her conduct in selecting a team of physicians, as well as the careful, cautious, reasoned, meticulous and methodical manner in which she approached her health care. (Evidence Code § 1250(a)(2); *Foss v. Anthony Industries* (1983) 139 Cal.App.3d 794; 800-801)

Consequently, objections to the e-mails exchanged by Drs. Swerdlow and Shivkumar and the

Secareas [Exhibit-3 (3.CT.847-860); Exhibit-4 (3.CT.868-881), Exhibit-9 (4.CT.906-919)] should have been overruled.

d. Objections to the admission of literature from a medical symposium should have been overruled in that they contained party admissions and were not offered to prove any fact requiring expert testimony

In opposition to the motions for summary judgment by the Regents, Drs. Swerdlow, Shivkumar, and Cesario, Valer introduced Exhibits 7 and 8, which included "Highlights of the 54th Annual Scientific

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Session of the American College of Cardiology" held March 6-9, 2005. (4.CT.898-899; 901-904) In those highlights, "Cesario et al. (13) (presented by Charles Swerdlow) hypothesized that monitoring of esophageal temperature may detect early temperature rises to prevent esophageal injury. They studied 12 patients using an esophageal temperature probe positioned at the level of the 8-mm ablation tip." (4.CT.899) Dr. Shivkumar is also named in Footnote 13. (4.CT.899)

Statements made by respondents, consistent with the statements above, were written by respondents and included in the "Abstracts of Original Contributions to be Presented at the American College of Cardiology 54th Annual Scientific Session, March 6-9, 2005,

Orlando, Florida." (4.CT.903)

Respondents objected to these exhibits on the grounds the exhibits were "articles and abstracts from medical journals." They claim that such medical texts are admissibly only in limited circumstances and when a foundation has been laid for them by a medical expert. They argue these texts are hearsay. (5.CT.1202) But, as noted above, these texts were admissible as exceptions to the hearsay rule because they contained party admissions. They are not medical texts used to criticize a medical treatment (see generally, *Gruckstein v. Lipsett* (1949) 93 Cal.App.2d 391, 400-404); they showed respondents were announcing to their medical colleagues that they were conducting medical research on the use of the esophageal temperature probe in an attempt to advance generalized knowledge on the diagnosis of the conditions leading to atrio-esophageal fistula formation, one of the ultimate issues in this case.

Appellant contends the court erred in that the objections interposed are without merit. (RT 36-37)

D. The Trial Court Erred in Granting the Summary Judgments

Erroneous granting of motion for summary judgment is denial of fair trial and reversible. (*Callahan v Chatsworth Park, Inc.* 204 Cal App 2d 597, 22 Cal Rptr 606 (1962))

Due Process Deprivation at MSJ Hearing (Appellant's Reply Brief)

[ARB: Page 44]

a. No waiver of defects in evidence

UCLA Respondents claim that Appellant has waived his right to appeal evidentiary issues. (RRB:13-15) However, this is not the case. (*Waiver, supra,?* :ARB:?) There was no "free choice," no waiver.

[ARB: Page 45]

There was a pure deprivation of due process and fairness in this matter. (See *Due Process Right Deprivation,* VII.C.1:AOB:47) Appellant could not be said to have voluntarily relinquished a right "for failure to perform," when that right had been "forcibly" taken.

[APFR: Page 18]

C. The CCP § 2015.5 objection ruling deprived Appellant of his Constitutional due process guarantees (page 10)

Appellant raised the matter of Due Process Right violations in this case in his Opening Brief. (AOB:47-49). During the hearing on the Summary Judgment motions in the trial court, Appellant's attorney asked to address evidentiary issues. The lower court responded:

> "I don't argue evidentiary objections. . . I just go ahead and read the paperwork, look at the objections and rule on them, so – because otherwise, we have speaking objections, and I don't do that." (RT 36:24-37:3)

The Opinion states at page 10-11, that:

> Plaintiff, however,

[APFR: Page 19]

> never filed any objections to Natale's declaration, and therefore waived the point [Citation] (See, e.g., *Rader v. Thrasher* (1972)

22 Cal.App.3d 883, 886.) [7]

Nothing in *Rader* addresses the situation complained of. This court relies on a *filing* of objections as the sole vehicle by which objections to evidence may be raised. The statute provides for no such restriction. The right to make objections orally, "at the hearing," is statutorily conferred. (CCP § 437c (b)(5)) Objections to evidence may be either filed (as the Court suggests) or made orally at the hearing on the motion, to wit:

> "A party desiring to make objections to evidence in the papers on a motion for summary judgment shall either submit objections in writing pursuant to rule 345 or make arrangements for a court reporter to be present at the hearing." (*City of Long Beach v. Farmers & Merchants Bank of Long Beach* (2000) 81 Cal.App.4th 780, 783 [81 Cal.App.4th 780; 97 Cal.Rptr.2d 140])

The trial court's refusal to hear those objections was arbitrary, did not follow the law and deprived this Appellant of his right to be heard. *Sierra Craft, Inc. v. Magnum Enterprises, Inc.*, 64 Cal.App.4th 1252, 1255-1256 [75 Cal.Rptr.2d 681] (1998))

"Waiver" is the voluntary relinquishment of a known right, or at most, "the loss of an opportunity or a right as a result of a party's failure to perform an act

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[7] In Findlaw (www.Findlaw.com), the actual cite is to page 889, not 886)

it is required to perform . . . ." (*Platt Pacific, Inc. v. Andelson* (1993) 6 Cal.4th 307, 315.)

In addition, requirements for waiver typically include that it was not the product of intimidation, coercion, or deception. The trial court's silencing Appellant's counsel from making any statement at all regarding evidence suggests both coercion and intimidation. (*People v. Clark* (1993) 5 Cal.4th 950, 986).

There was no "free choice," no waiver. There was a pure deprivation of due process and fairness in this matter. Appellant could not be said to have voluntarily relinquished a right "for failure to perform," when that right had been "forcibly" taken.

Consequently, the Opinion violates Appellant's due process rights, guaranteed by both the California and U. S. Constitutions, when it declared that only *filed* objections would be recognized. (*Saleeby v. State Bar* 39 Cal. 3d 547, 565 [216 Cal. Rptr. 367, 702 P.2d 525] (1985); *People v. Ramirez, supra*, 25 Cal.3d at page 268; *Hernandez v. Department of Motor Vehicles* 30 Cal. 3d at page 81, fn. 12; U.S. Constitution, 5th and 14th Amendments; California Constitution, article I, § 15, cl. 7.).

The Court's ruling allowing the Natale Declaration cannot withstand Constitutional scrutiny and should be reversed, along with the Motion for Summary Judgment of Defendants Regents of the University of California, David Cesario, M. D. and Kalyanam Shivkumar, M.D. (*Callahan v Chatsworth Park, Inc., supra*, 204 Cal.App 2d at page 610)

The same line of reasoning applies to Appellant-

plaintiff's evidentiary issues. (AOB:49-53)

Although, as a general rule, an appellate court will not review an issue that was not raised by some proper method by a party in the trial court, a "noncurable defect of substance where the question is one of law" is not a matter that falls within this rule. (9 Witkin, Cal. Procedure (4th ed. 1997) Appeal, § 394, p. 444.) A "matter involving the public interest or the due administration of justice" also is not. (Id. at p. 450.) The issue of a party's right to address evidentiary matters at a summary judgment motion hearing is not one of "private convenience," but public policy. Thus, it is properly before this court. (*United California Bank v. Bottler* (1971) 16 Cal.App.3d 610 , 616; *People v. Blanco* (1992) 10 Cal. App. 4th 1167, 1172-1173 [13 Cal. Rptr. 2d 176]; generally, *State of California ex rel. Public Works Bd. v. Bragg* (1986) 183 Cal.App.3d 1018, 1023-1024.)

For the reasons stated above, Appellant requests a rehearing on this matter. However, if the Court believes there is no right to present evidentiary objections in person at the summary judgment hearing, Appellant asks that this Court explain its reasoning and publish the results, as no published decision to date has ruled either that oral objections to evidence could be entirely precluded at a summary judgment hearing or that a trial court's refusal to hear such objections could be imputed to the party before the court as a "voluntary relinquishment." (California Rules of Court, Rule 8.1105, Rule 8.1120)

Due Process Deprivation at MSJ Hearing (California Supreme Court Petition for Review)

[SPFR: Page 16]

A. Freedom From Arbitrary Adjudicative Procedures

Under the California Constitution 'freedom from arbitrary adjudicative procedures is a substantive element of one's liberty' so that 'when an individual is subjected to deprivatory governmental action, he always has a due process liberty interest [...].'" (*Hernandez v. Department of Motor Vehicles* (1981) 30 Cal.3d 70, 81, fn. 12 [177 Cal. Rptr. 566; 634 P.2d 917])

[SPFR: Page 17]

The touchstone of due process is freedom from arbitrary governmental action. (*Ponte V. Real* (1985) 105 S.Ct. 2192 [471 U.S. 491]) "[...] due process safeguards required for protection of an individual's statutory interests must be analyzed in the context of the principle that freedom from arbitrary adjudicative procedures is a substantive element of one's liberty. [Citation.]" (*People v. Ramirez* (1979) 25 Cal.3d 260, 268 [599 P.2d 622; 158 Cal.Rptr. 316])

[SPFR: Page 27]

D. This Court should grant review to determine whether the trial court's refusal to

allow counsel to be heard on evidentiary issues deprived Petitioner of his Constitutional due process guarantees and improperly excluded admissions of experimentation

1. The CCP § 2015.5 objection

Appellant raised and addressed the matter of Due Process Right violations in this case in all briefs. (AOB:47-49, ARB:44-45 and especially APR:18-22).

To review, during the hearing on the Summary Judgment motions in the trial court, Appellant's attorney asked to address evidentiary issues. The lower court responded:

> "I don't argue evidentiary objections. . . I just go ahead and read the paperwork, look at the objections and rule on them, so – because otherwise, we have speaking objections, and I don't do that." (AOB:47)

The Opinion states at page 10-11, that:

> Plaintiff, however, never filed any objections to Natale's declaration, and therefore waived the point [Citation] (See, e.g., *Rader v. Thrasher* (1972) 22 Cal.App.3d 883, 886.) [8]

But, on 22 December 2008, the Court of Appeal modified its opinion. In the Modified Opinion, the Court

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[8] In Findlaw (www.Findlaw.com), the actual cite is to page 889, not 886)

deletes the above-quoted sentence and its citation to *Rader*. The Modification then engages in a lengthy speculation of possibilities regarding the myriad of ways Plaintiff counsel might have raised objections to the Natale Declaration.

But, a legal inference cannot flow from the nonexistence of a fact; [...]. An inference may not be based on suspicion alone, or on imagination, speculation, supposition, surmise, conjecture or guesswork. (*Traxler v Thompson* (1970) 4 Cal App 3d 278, 288 [84 Cal Rptr 211])

The Modification goes on to state that "Significantly, plaintiff's counsel requested the opportunity to *argue* objections, and never informed the court he wished to make new objections." This Petitioner is at a loss to understand what the difference between "argue" and "make new" could be in this context and how one would come to make a conscious choice between the two at any given moment

In the "spirit of parsing" then, it would not have mattered how counsel introduced his desire to speak or "object" to the evidence. The trial court wasn't going to allow any "speaking objections" of any kind by Plaintiff counsel.

Moreover, the summary judgment statute provides for no such restriction. The right to make objections orally, "at the hearing," is statutorily conferred. (CCP § 437c (b)(5)) Objections to evidence may be either filed or made orally at the hearing on the motion; See also *City of Long Beach v. Farmers & Merchants Bank of Long Beach* (2000) 81 Cal.App.4th 780, 783 [81 Cal.App.4th 780; 97 Cal.Rptr.2d 140])

The trial court's refusal to hear those objections was arbitrary, did not follow the law and deprived this Appellant of his right to be heard.(See *Fair Trial, supra*, at page ?)

Consequently, the ruling allowing the Natale Declaration cannot withstand Constitutional scrutiny. Both the Opinion and Modification violate Petitioner-Appellant's due process rights, guaranteed by both the California and U. S. Constitutions, when it arbitrarily ruled that only objections that somehow met with its approval would be recognized. (See: *Freedom From Arbitrary Adjudicative Procedures*, at page 16)